



CERTIFICATE

EC Certificate
Design Examination According to
Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-769

We hereby declare that a design examination has been carried out on the devices listed hereafter following the requirements of the national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed thereafter conforms with the relevant provisions of Annex II Section 4 of the Directive 93/42/EEC on medical devices as transposed into national legislation.

Organization

Speciality Fibres and Materials Limited

Galaxy House 31 Herald Way Binley Industrial Estate Coventry CV3 2RQ, UK

Product: Venus Ag

The products defined at the enclosure which is the part of this certificate and contains seven (7) page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Full quality assurance system according to Medical Devices Directive 93/42/EEC Annex-II Section 3 certificate is also mandatory for class III devices covered by this certificate.

Report Number: M.5991.01

Expiry Date: 27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

05 May 2021, Istanbul, Turkey



Enclosure of the EC Certificate:

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Design Examination

Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-769

Concerned medical devices;

Product: Venus Ag

Product Code	Commercial Name/Dimensions
FV000001	Venus Ag 120 5x5cm
FV000002	Venus Ag 120 10x10cm
FV000003	Venus Ag 120 10x12.5cm
FV000004	Venus Ag 120 15x15cm
FV000005	Venus Ag 120 2x45
FV000006	Venus Ag 160 5x5cm
FV000007	Venus Ag 160 10x10cm
FV000008	Venus Ag 160 10x12.5cm
FV000009	Venus Ag 160 15x15cm
FV000010	Venus Ag 160 2x45
FV000011	Venus Ag 200 5x5cm
FV000012	Venus Ag 200 10x10cm
FV000013	Venus Ag 200 10x12.5cm
FV000014	Venus Ag 200 15x15cm
FV000015	Venus Ag 200 2x45
FV000016	ExuCel Ag 120 5x5cm
FV000017	ExuCel Ag 120 10x10cm
FV000018	ExuCel Ag 120 10x12.5cm
FV000019	ExuCel Ag 120 15x15cm
FV000020	ExuCel Ag 120 2x45
FV000021	ExuCel Ag 160 5x5cm
FV000022	ExuCel Ag 160 10x10cm
FV000023	ExuCel Ag 160 10x12.5cm
FV000024	ExuCel Ag 160 15x15cm
FV000025	ExuCel Ag 160 2x45

Muhteşem Gökhan Yücel
Head of Notified Body

05 May 2021, Istanbul, Turkey



CERTIFICATE

Enclosure of the EC Certificate:

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Design Examination

Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-769

Concerned medical devices;

Product: Venus Ag

Product Code	Commercial Name/Dimensions
FV000026	ExuCel Ag 200 5x5cm
FV000027	ExuCel Ag 200 10x10cm
FV000028	ExuCel Ag 200 10x12.5cm
FV000029	ExuCel Ag 200 15x15cm
FV000030	ExuCel Ag 200 2x45
FV000031	ExuPro Cel Ag 120 5x5cm
FV000032	ExuPro Cel Ag 120 10x10cm
FV000033	ExuPro Cel Ag 120 10x12.5cm
FV000034	ExuPro Cel Ag 120 15x15cm
FV000035	ExuPro Cel Ag 120 2x45
FV000036	ExuPro Cel Ag 160 5x5cm
FV000037	ExuPro Cel Ag 160 10x10cm
FV000038	ExuPro Cel Ag 160 10x12.5cm
FV000039	ExuPro Cel Ag 160 15x15cm
FV000040	ExuPro Cel Ag 160 2x45
FV000041	ExuPro Cel Ag 200 5x5cm
FV000042	ExuPro Cel Ag 200 10x10cm
FV000043	ExuPro Cel Ag 200 10x12.5cm
FV000044	ExuPro Cel Ag 200 15x15cm
FV000045	ExuPro Cel Ag 200 2x45
FV000046	NanoCel Ag 120 5x5cm
FV000047	NanoCel Ag 120 10x10cm
FV000048	NanoCel Ag 120 10x12.5cm
FV000049	NanoCel Ag 120 15x15cm
FV000050	NanoCel Ag 120 2x45



Muhtesem Gökhan Yücel
Head of Notified Body

05 May 2021, Istanbul, Turkey



Enclosure of the EC Certificate:

Design Examination

Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-769

Concerned medical devices;

Product: Venus Ag

Product Code	Commercial Name/Dimensions
FV000051	NanoCel Ag 160 5x5cm
FV000052	NanoCel Ag 160 10x10cm
FV000053	NanoCel Ag 160 10x12.5cm
FV000054	NanoCel Ag 160 15x15cm
FV000055	NanoCel Ag 160 2x45
FV000056	NanoCel Ag 200 5x5cm
FV000057	NanoCel Ag 200 10x10cm
FV000058	NanoCel Ag 200 10x12.5cm
FV000059	NanoCel Ag 200 15x15cm
FV000060	NanoCel Ag 200 2x45
FV000061	LunaFiber Ag 120 5x5cm
FV000062	LunaFiber Ag 120 10x10cm
FV000063	LunaFiber Ag 120 10x12.5cm
FV000064	LunaFiber Ag 120 15x15cm
FV000065	LunaFiber Ag 120 2x45
FV000066	LunaFiber Ag 160 5x5cm
FV000067	LunaFiber Ag 160 10x10cm
FV000068	LunaFiber Ag 160 10x12.5cm
FV000069	LunaFiber Ag 160 15x15cm
FV000070	LunaFiber Ag 160 2x45
FV000071	LunaFiber Ag 200 5x5cm
FV000072	LunaFiber Ag 200 10x10cm
FV000073	LunaFiber Ag 200 10x12.5cm
FV000074	LunaFiber Ag 200 15x15cm
FV000075	LunaFiber Ag 200 2x45



Muhteşem Gökhan Yücel
Head of Notified Body

05 May 2021, Istanbul, Turkey



Enclosure of the EC Certificate:

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Design Examination

Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-769

Concerned medical devices;

Product: Venus Ag

Product Code	Commercial Name/Dimensions
FV000076	Sequana Ag 120 5x5cm
FV000077	Sequana Ag 120 10x10cm
FV000078	Sequana Ag 120 10x12.5cm
FV000079	Sequana Ag 120 15x15cm
FV000080	Sequana Ag 120 2x45
FV000081	Sequana Ag 160 5x5cm
FV000082	Sequana Ag 160 10x10cm
FV000083	Sequana Ag 160 10x12.5cm
FV000084	Sequana Ag 160 15x15cm
FV000085	Sequana Ag 160 2x45
FV000086	Sequana Ag 200 5x5cm
FV000087	Sequana Ag 200 10x10cm
FV000088	Sequana Ag 200 10x12.5cm
FV000089	Sequana Ag 200 15x15cm
FV000090	Sequana Ag 200 2x45
FV000091	SequanaCel Ag 120 5x5cm
FV000092	SequanaCel Ag 120 10x10cm
FV000093	SequanaCel Ag 120 10x12.5cm
FV000094	SequanaCel Ag 120 15x15cm
FV000095	SequanaCel Ag 120 2x45
FV000096	SequanaCel Ag 160 5x5cm
FV000097	SequanaCel Ag 160 10x10cm
FV000098	SequanaCel Ag 160 10x12.5cm
FV000099	SequanaCel Ag 160 15x15cm
FV000100	SequanaCel Ag 160 2x45



Muhteşem Gökhan Yücel
Head of Notified Body

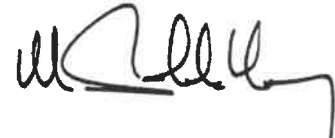
05 May 2021, Istanbul, Turkey

Enclosure of the EC Certificate:**Design Examination****Medical Devices Directive 93/42/EEC Annex-II Section 4****Certificate Number: 1984-MDD-21-769**

Concerned medical devices;

Product: Venus Ag

Product Code	Commercial Name/Dimensions
FV000101	SequanaCel Ag 200 5x5cm
FV000102	SequanaCel Ag 200 10x10cm
FV000103	SequanaCel Ag 200 10x12.5cm
FV000104	SequanaCel Ag 200 15x15cm
FV000105	SequanaCel Ag 200 2x45
FV000106	SequanaFiber Ag 120 5x5cm
FV000107	SequanaFiber Ag 120 10x10cm
FV000108	SequanaFiber Ag 120 10x12.5cm
FV000109	SequanaFiber Ag 120 15x15cm
FV000110	SequanaFiber Ag 120 2x45
FV000111	SequanaFiber Ag 160 5x5cm
FV000112	SequanaFiber Ag 160 10x10cm
FV000113	SequanaFiber Ag 160 10x12.5cm
FV000114	SequanaFiber Ag 160 15x15cm
FV000115	SequanaFiber Ag 160 2x45
FV000116	SequanaFiber Ag 200 5x5cm
FV000117	SequanaFiber Ag 200 10x10cm
FV000118	SequanaFiber Ag 200 10x12.5cm
FV000119	SequanaFiber Ag 200 15x15cm
FV000120	SequanaFiber Ag 200 2x45
FV000121	Sirona Ag 120 5x5cm
FV000122	Sirona Ag 120 10x10cm
FV000123	Sirona Ag 120 10x12.5cm
FV000124	Sirona Ag 120 15x15cm
FV000125	Sirona Ag 120 2x45



Muhteşem Gökhan Yücel
Head of Notified Body

05 May 2021, Istanbul, Turkey



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Design Examination


Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-769

Concerned medical devices;

Product: Venus Ag

Product Code	Commercial Name/Dimensions
FV000126	Sirona Ag 160 5x5cm
FV000127	Sirona Ag 160 10x10cm
FV000128	Sirona Ag 160 10x12.5cm
FV000129	Sirona Ag 160 15x15cm
FV000130	Sirona Ag 160 2x45
FV000131	Sirona Ag 200 5x5cm
FV000132	Sirona Ag 200 10x10cm
FV000133	Sirona Ag 200 10x12.5cm
FV000134	Sirona Ag 200 15x15cm
FV000135	Sirona Ag 200 2x45
FV000136	SironaCel Ag 120 5x5cm
FV000137	SironaCel Ag 120 10x10cm
FV000138	SironaCel Ag 120 10x12.5cm
FV000139	SironaCel Ag 120 15x15cm
FV000140	SironaCel Ag 120 2x45
FV000141	SironaCel Ag 160 5x5cm
FV000142	SironaCel Ag 160 10x10cm
FV000143	SironaCel Ag 160 10x12.5cm
FV000144	SironaCel Ag 160 15x15cm
FV000145	SironaCel Ag 160 2x45
FV000146	SironaCel Ag 200 5x5cm
FV000147	SironaCel Ag 200 10x10cm
FV000148	SironaCel Ag 200 10x12.5cm
FV000149	SironaCel Ag 200 15x15cm
FV000150	SironaCel Ag 200 2x45



Muhtesem Gökhan Yücel
Head of Notified Body

05 May 2021, Istanbul, Turkey



Enclosure of the EC Certificate:

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Design Examination

Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-769

Concerned medical devices;

Product: Venus Ag

Product Code	Commercial Name/Dimensions
FV000151	SironaFiber Ag 120 5x5cm
FV000152	SironaFiber Ag 120 10x10cm
FV000153	SironaFiber Ag 120 10x12.5cm
FV000154	SironaFiber Ag 120 15x15cm
FV000155	SironaFiber Ag 120 2x45
FV000156	SironaFiber Ag 160 5x5cm
FV000157	SironaFiber Ag 160 10x10cm
FV000158	SironaFiber Ag 160 10x12.5cm
FV000159	SironaFiber Ag 160 15x15cm
FV000160	SironaFiber Ag 160 2x45
FV000161	SironaFiber Ag 200 5x5cm
FV000162	SironaFiber Ag 200 10x10cm
FV000163	SironaFiber Ag 200 10x12.5cm
FV000164	SironaFiber Ag 200 15x15cm
FV000165	SironaFiber Ag 200 2x45

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984



Muhteşem Gökhan Yücel
Head of Notified Body

05 May 2021, Istanbul, Turkey

MDCG 2020-3 DEĞİŞİKLİK DOĞRULAMA FORMU

MDCG 2020-3 Change Verification Form



Tarih: Date:	18.07.2023
Referans No: Reference No:	MY-21-002017-Rev.01

Dear Sir/Madam,

Your following proposed change is reviewed according to the MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.

EC Sertifika Bilgileri Information on EC Certificate															
EC Sertifika No: EC Certificate No:	1984-MDD-21-752, 1984-MDD-21-769														
Revizyon bilgileri: Revision:	1984-MDD-21-752 Rev.01 (05 May 2021), 1984-MDD-21-769 Rev.00 (05 May 2021)														
İmalatçı : Manufacturer:	Speciality Fibres and Materials Limited														
Son Geçerlilik Tarihi: Expiry Date:	27.05.2024														
Değişiklik Önerisine İlişkin Bilgiler Information on Proposed Change															
Değişiklik konusu: Subject of Change:	<p>Speciality Fibres and Materials Limited would like to swap the models name listed below for new ones: as listed below in table 1</p> <p>Table 1: Proposed Replacement for Venus AG Model Names</p> <table border="1"><thead><tr><th>Models (on current CE certificate 1984 MDD-21-752 Annex II.3 and 1984-MDD-21-769 Annex II.4)</th><th>Replace with</th></tr></thead><tbody><tr><td>Sequana Ag</td><td>Advagel Ag</td></tr><tr><td>SequanaCel Ag</td><td>ActivHeal Aquafiber Ag + Extra</td></tr><tr><td>SequanaFiber Ag</td><td>Avarus Ag Silver Gelling Fibre</td></tr><tr><td>Sirona Ag</td><td>Celox Burn Dressing</td></tr><tr><td>SironaCel Ag</td><td>Silvapro Plus</td></tr><tr><td>SironaFiber Ag</td><td>Suprasorb Liquacel Ag</td></tr></tbody></table>	Models (on current CE certificate 1984 MDD-21-752 Annex II.3 and 1984-MDD-21-769 Annex II.4)	Replace with	Sequana Ag	Advagel Ag	SequanaCel Ag	ActivHeal Aquafiber Ag + Extra	SequanaFiber Ag	Avarus Ag Silver Gelling Fibre	Sirona Ag	Celox Burn Dressing	SironaCel Ag	Silvapro Plus	SironaFiber Ag	Suprasorb Liquacel Ag
Models (on current CE certificate 1984 MDD-21-752 Annex II.3 and 1984-MDD-21-769 Annex II.4)	Replace with														
Sequana Ag	Advagel Ag														
SequanaCel Ag	ActivHeal Aquafiber Ag + Extra														
SequanaFiber Ag	Avarus Ag Silver Gelling Fibre														
Sirona Ag	Celox Burn Dressing														
SironaCel Ag	Silvapro Plus														
SironaFiber Ag	Suprasorb Liquacel Ag														

The implementation of the above change proposed by Speciality Fibres and Materials Limited does not represent a significant change in the design and usage purpose within the scope of MDR Article 120(3).

The above-mentioned EC certificate is valid until its expiration date and is subject to the successful completion of periodic surveillance audits.

This letter is valid when presented together with the EC Certificate mentioned above.

Sincerely,

Mustafa Serkan Sevimli
Medical Devices Division Manager



Speciality Fibres and Materials Limited

Address: Galaxy House 31 Herald Way Binley Industrial Estate,
Coventry CV3 2RQ, UK

Date: 12.10.2022

Ref No: MY-22-002328

Kiwa Belgelendirme Hizmetleri A.Ş.

İ.T.O.S.B 9. Cadde No: 15

Tepeören Mevkii PK 34959

Tuzla İstanbul

Türkiye

Tel. +90 216 593 25 75

Faks +90 216 593 25 74

posta@kiwa.com.tr

www.kiwa.com

www.1kiwa.com

To Whom It May Concern,

As we Kiwa that confirms that Models on the CE Full Quality Assurance Certificate (1984-MDD-21-752 Annex II.3 Rev.01) and EC Design Examination Certificates (1984-MDD-21-769 Annex II.4 Rev. 1) are the same, that is the word Models on the design examination and full quality assurance certificates are the same as the word Brands on the amendment document (MY-21-002017).

Yours Sincerely,

Mehmet Fevzi Gülünay
Deputy General Manager


KIWA
BELGELENDİRME HİZMETLERİ A.Ş.
Eski Ankara Asfaltı İstanbul Tuzla Çarşısı
İ.T.O.S.B.) 9. Cad. No:15 Tepeören Mevkii
Tuzla V.D. 620 053 0464 Tlc. Sic. No:365270
Mersis No: 0670 0530 4640 0001

MDCG 2020-3 DEĞİŞİKLİK DOĞRULAMA FORMU
MDCG 2020-3 Change Verification Form



Tarih: Date:	07.09.2023
Referans No: Reference No:	MY-23-002495 rev.01

Dear Sir/Madam,

Your following proposed change is reviewed according to the MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.

EC Sertifika Bilgileri Information on EC Certificate	
EC Sertifika No: EC Certificate No:	1984-MDD-21-752, 1984-MDD-21-754, 1984-MDD-21-769
Revizyon bilgileri: Revision:	1984-MDD-21-752 Rev.01 (05.05.2021), 1984-MDD-21-754 Rev.00 (16.04.2021), 1984-MDD-21-769 Rev.00 (05.05.2021)
İmalatçı : Manufacturer:	SPECIALITY FIBRES AND MATERIALS LIMITED
Son Geçerlilik Tarihi: Expiry Date:	27.05.2024
Değişiklik Önerisine İlişkin Bilgiler Information on Proposed Change	
Değişiklik konusu: Subject of Change:	<p>For 1984-MDD-21-769 Annex II including Section 4 (Venus Ag):</p> <p>1984-MDD-21-769 (Venus Ag) certificate includes Sequana Fiber Aga model name , the “Sequana Fiber Ag” brand (model) name was replaced with” Avarus Ag Silver Gelling Fibre” in 2021 (Kiwa MDCG 2020-3 Change Verification Form, Reference No: MY-21-002017, date: 25.11.2021). Now “Avarus Ag Silver Gelling Fibre” brand (model) name is going to be replaced with “DuraFiber Ag Pro” brand(model) name and relevant product codes (ref numbers) is going to be changed.</p> <p>A) The full list of DuraFiber Ag Pro variants is attached to this amendment as Appendix 1.</p> <p>For 1984-MDD-21-754 Annex II including Section 4 (Silver Alginate):</p> <p>Changing product codes for the four variants of the Suprasorb A+Ag</p> <p>B) The full list of Suprasorb A+Ag variants is attached to this amendment as Appendix 2.</p>

The implementation of the above change proposed by SPECIALITY FIBRES AND MATERIALS LIMITED does not represent a significant change in the design and usage purpose within the scope of MDR Article 120(3).

The above-mentioned EC certificate is valid until its expiration date and is subject to the successful completion of periodic surveillance audits.

This letter is valid when presented together with the EC Certificate mentioned above.

Sincerely,

Mustafa Serkan Sevimli
Medical Devices Division Manager

Amendment Kiwa MY-23-002495 Appendix 1

Product: Venus Ag

Model: DuraFiber Ag Pro

Concerned medical devices;

<u>Product Code / References</u> <u>(codes on DofCs)</u>	<u>Product Variants</u> <u>(Commercial Name / Dimensions)</u>
FV000970	DuraFiber Ag Pro 120 10x10cm
FV000973	DuraFiber Ag Pro 120 10x12.5cm
FV000974	DuraFiber Ag Pro 120 10x12cm
FV000975	DuraFiber Ag Pro 120 10x20cm
FV000976	DuraFiber Ag Pro 120 15x15cm
FV000977	DuraFiber Ag Pro 120 15x20cm
FV000978	DuraFiber Ag Pro 120 1x30cm
FV000979	DuraFiber Ag Pro 120 1x45cm
FV000980	DuraFiber Ag Pro 120 20x20cm
FV000981	DuraFiber Ag Pro 120 20x30cm
FV000982	DuraFiber Ag Pro 120 2x30cm
FV000983	DuraFiber Ag Pro 120 2x45cm
FV000984	DuraFiber Ag Pro 120 4x10cm
FV000985	DuraFiber Ag Pro 120 4x20cm
FV000986	DuraFiber Ag Pro 120 4x30cm
FV000987	DuraFiber Ag Pro 120 5x5cm
FV000971	DuraFiber Ag Pro 160 10x10cm
FV000988	DuraFiber Ag Pro 160 10x12.5cm
FV000989	DuraFiber Ag Pro 160 10x12cm
FV000990	DuraFiber Ag Pro 160 10x20cm
FV000991	DuraFiber Ag Pro 160 15x15cm
FV000992	DuraFiber Ag Pro 160 15x20cm
FV000993	DuraFiber Ag Pro 160 1x30cm
FV000994	DuraFiber Ag Pro 160 1x45cm
FV000995	DuraFiber Ag Pro 160 1x45cm
FV000996	DuraFiber Ag Pro 160 20x20cm
FV000997	DuraFiber Ag Pro 160 20x30cm
FV000998	DuraFiber Ag Pro 160 2x30cm
FV000999	DuraFiber Ag Pro 160 2x45cm
FV001000	DuraFiber Ag Pro 160 4x10cm
FV001001	DuraFiber Ag Pro 160 4x20cm
FV001002	DuraFiber Ag Pro 160 4x30cm
FV000972	DuraFiber Ag Pro 200 10x10cm
FV001003	DuraFiber Ag Pro 200 10x12.5cm

Product Code / References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FV001004	DuraFiber Ag Pro 200 10x12cm
FV001005	DuraFiber Ag Pro 200 10x20cm
FV001006	DuraFiber Ag Pro 200 15x15cm
FV001007	DuraFiber Ag Pro 200 15x20cm
FV001008	DuraFiber Ag Pro 200 1x30cm
FV001009	DuraFiber Ag Pro 200 1x45cm
FV001010	DuraFiber Ag Pro 200 20x20cm
FV001011	DuraFiber Ag Pro 200 20x30cm
FV001012	DuraFiber Ag Pro 200 2x30cm
FV001013	DuraFiber Ag Pro 200 2x45cm
FV001014	DuraFiber Ag Pro 200 4x10cm
FV001015	DuraFiber Ag Pro 200 4x20cm
FV001016	DuraFiber Ag Pro 200 4x30cm
FV001017	DuraFiber Ag Pro 200 5x5cm

Amendment Kiwa MY-23-002495 Appendix 2

Product: Silver Alginate

Model: Suprasorb A+Ag

<u>Product Codes/References</u> <u>(codes on DofCs)</u>	<u>Product Variants</u> <u>(Commercial Name/Dimensions)</u>
20571	Suprasorb A+Ag AgLI30 10x10cm
FAI70655	Suprasorb A+Ag AgLI30 10x12.5cm
FAI70855	Suprasorb A+Ag AgLI30 10x12cm
20572	Suprasorb A+Ag AgLI30 10x20cm
FAI70671	Suprasorb A+Ag AgLI30 15x15cm
FAI70679	Suprasorb A+Ag AgLI30 15x20cm
FAI70859	Suprasorb A+Ag AgLI30 1x30cm
FAI70865	Suprasorb A+Ag AgLI30 1x45cm
FAI70866	Suprasorb A+Ag AgLI30 20x20cm
FAI70687	Suprasorb A+Ag AgLI30 20x30cm
FAI70853	Suprasorb A+Ag AgLI30 2x30cm
FAI70854	Suprasorb A+Ag AgLI30 2x45cm
FAI70856	Suprasorb A+Ag AgLI30 4x10cm
FAI70857	Suprasorb A+Ag AgLI30 4x20cm
FAI70858	Suprasorb A+Ag AgLI30 4x30cm
20570	Suprasorb A+Ag AgLI30 5x5cm
FAI70868	Suprasorb A+Ag AgW330 10x10cm
FAI70869	Suprasorb A+Ag AgW330 10x12.5cm
FAI70874	Suprasorb A+Ag AgW330 10x12cm
FAI70870	Suprasorb A+Ag AgW330 10x20cm
FAI70871	Suprasorb A+Ag AgW330 15x15cm
FAI70872	Suprasorb A+Ag AgW330 15x20cm
FAI70879	Suprasorb A+Ag AgW330 1x30cm
FAI70880	Suprasorb A+Ag AgW330 1x45cm
FAI70875	Suprasorb A+Ag AgW330 20x20cm
FAI70873	Suprasorb A+Ag AgW330 20x30cm
20573	Suprasorb A+Ag AgW330 2x30cm
FAI70637	Suprasorb A+Ag AgW330 2x45cm
FAI70876	Suprasorb A+Ag AgW330 4x10cm
FAI70877	Suprasorb A+Ag AgW330 4x20cm
FAI70878	Suprasorb A+Ag AgW330 4x30cm
FAI70867	Suprasorb A+Ag AgW330 5x5cm

MDCG 2020-3 DEĞİŞİKLİK DOĞRULAMA FORMU

MDCG 2020-3 Change Verification Form



Tarih: Date:	07.09.2023
Referans No: Reference No:	MY-23-002511 rev.01

Dear Sir/Madam,

Your following proposed change is reviewed according to the MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.

EC Sertifika Bilgileri Information on EC Certificate	
EC Sertifika No: EC Certificate No:	1984-MDD-21-752, 1984-MDD-21-753, 1984-MDD-21-754, 1984-MDD-21-769,
Revizyon bilgileri: Revision:	1984-MDD-21-752 Rev.01 (05.05.2021), 1984-MDD-21-753 Rev.00 (16.04.2021), 1984-MDD-21-754 Rev.00 (16.04.2021), 1984-MDD-21-769 Rev.00 (05.05.2021)
İmalatçı : Manufacturer:	Speciality Fibres and Materials Limited
Son Geçerlilik Tarihi: Expiry Date:	27.05.2024
Değişiklik Önerisine İlişkin Bilgiler Information on Proposed Change	
Değişiklik konusu: Subject of Change:	<p>1- Replacing the word "brands" on the SFM product names with the word "models" to align with the Kiwa wording on the CE certificate</p> <p>2-) Providing to Kiwa the full list of product REF codes assigned to the variants of the models under the certificate 1984-MDD-21-769 Annex II including Section 4 (Venus Ag only) as amended by the amendment MY-21-002017.</p> <p>3-) Adding new model variant (new sizes) to model name for Pluto Ag, Venus Ag, AgL130 (Silver Alginate gsm) and AgW330 (Silver Alginate gsm) within the current range</p> <p>4-) Substituting current cleared model names on the current CE certificate for new model names (replace the model name "NanoCel" with "Askina® Calgitrol® Ag+"). And Adding new model variant (new sizes).</p> <p>5-) Replacing the current product codes for the Pluto Ag variants with updated references for the product sizes.</p> <p>6-) Adding a new sterilization supplier, Sterigenics Company to the SFM list of critical suppliers for gamma sterilisation for Pluto Ag, Venus Ag and Silver Alginate product families within the defined specifications</p> <p>A) The full list of Venus Ag models and their variants are listed in this amendment as Appendix 1 B) The full list of Pluto Ag models and their variants are listed in this amendment as Appendix 2 C) The full list of Silver Alginate models and their variants are listed in this amendment as Appendix 3</p>

The implementation of the above change proposed by Speciality Fibres and Materials Limited does not represent a significant change in the design and usage purpose within the scope of MDR Article 120(3).

The above-mentioned EC certificate is valid until its expiration date and is subject to the successful completion of periodic surveillance audits.

This letter is valid when presented together with the EC Certificate mentioned above.

Sincerely,

Mustafa Serkan Sevimli
Medical Devices Division Manager

S.M.FR.037/05.11.2021/R1

Kiwa Belgelendirme Hizmetleri A.Ş.
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Amendment Kiwa MY-23-002511 Appendix 1

Product: Venus Ag

Model: Venus Ag

Concerned medical devices;

Product Code/References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FV000002	Venus Ag 120 10x10cm
FV000003	Venus Ag 120 10x12.5cm
FV000358	Venus Ag 120 10x12cm
FV000351	Venus Ag 120 10x20cm
FV000004	Venus Ag 120 15x15cm
FV000350	Venus Ag 120 15x20cm
FV000353	Venus Ag 120 1x30cm
FV000352	Venus Ag 120 1x45cm
FV000360	Venus Ag 120 20x20cm
FV000359	Venus Ag 120 20x30cm
FV000354	Venus Ag 120 2x30cm
FV000005	Venus Ag 120 2x45cm
FV000357	Venus Ag 120 4x10cm
FV000356	Venus Ag 120 4x20cm
FV000355	Venus Ag 120 4x30cm
FV000001	Venus Ag 120 5x5cm
FV000007	Venus Ag 160 10x10cm
FV000008	Venus Ag 160 10x12.5cm
FV000348	Venus Ag 160 10x12cm
FV000341	Venus Ag 160 10x20cm
FV000340	Venus Ag 160 15x15cm
FV000340	Venus Ag 160 15x20cm
FV000343	Venus Ag 160 1x30cm
FV000342	Venus Ag 160 1x45cm
FV000361	Venus Ag 160 20x20cm
FV000349	Venus Ag 160 20x30cm
FV000344	Venus Ag 160 2x30cm
FV000010	Venus Ag 160 2x45cm
FV000347	Venus Ag 160 4x10cm
FV000346	Venus Ag 160 4x20cm
FV000345	Venus Ag 160 4x30cm
FV000006	Venus Ag 160 5x5cm
FV000012	Venus Ag 200 10x10cm
FV000013	Venus Ag 200 10x12.5cm
FV000338	Venus Ag 200 10x12cm
FV000331	Venus Ag 200 10x20cm
FV000014	Venus Ag 200 15x15cm
FV000330	Venus Ag 200 15x20cm

Product Code / References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FV000333	Venus Ag 200 1x30cm
FV000332	Venus Ag 200 1x45cm
FV000362	Venus Ag 200 20x20cm
FV000339	Venus Ag 200 20x30cm
FV000334	Venus Ag 200 2x30cm
FV000015	Venus Ag 200 2x45cm
FV000337	Venus Ag 200 4x10cm
FV000336	Venus Ag 200 4x20cm
FV000335	Venus Ag 200 4x30cm
FV000011	Venus Ag 200 5x5cm

Model: ExuCel Ag

Concerned medical devices;

Product Code / References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FV000017	ExuCel Ag 120 10x10cm
FV000018	ExuCel Ag 120 10x12.5cm
FV000603	ExuCel Ag 120 10x12cm
FV000604	ExuCel Ag 120 10x20cm
FV000019	ExuCel Ag 120 15x15cm
FV000605	ExuCel Ag 120 15x20cm
FV000606	ExuCel Ag 120 1x30cm
FV000607	ExuCel Ag 120 1x45cm
FV000608	ExuCel Ag 120 20x20cm
FV000609	ExuCel Ag 120 20x30cm
FV000610	ExuCel Ag 120 2x30cm
FV000020	ExuCel Ag 120 2x45cm
FV000611	ExuCel Ag 120 4x10cm
FV000612	ExuCel Ag 120 4x20cm
FV000613	ExuCel Ag 120 4x30cm
FV000016	ExuCel Ag 120 5x5cm
FV000022	ExuCel Ag 160 10x10cm
FV000023	ExuCel Ag 160 10x12.5cm
FV000614	ExuCel Ag 160 10x12cm
FV000615	ExuCel Ag 160 10x20cm
FV000024	ExuCel Ag 160 15x15cm
FV000616	ExuCel Ag 160 15x20cm
FV000617	ExuCel Ag 160 1x30cm
FV000618	ExuCel Ag 160 1x45cm
FV000619	ExuCel Ag 160 20x20cm
FV000620	ExuCel Ag 160 20x30cm
FV000621	ExuCel Ag 160 2x30cm
FV000025	ExuCel Ag 160 2x45cm
FV000622	ExuCel Ag 160 4x10cm
FV000623	ExuCel Ag 160 4x20cm
FV000624	ExuCel Ag 160 4x30cm
FV000021	ExuCel Ag 160 5x5cm
FV000027	ExuCel Ag 200 10x10cm
FV000028	ExuCel Ag 200 10x12.5cm
FV000625	ExuCel Ag 200 10x12cm
FV000626	ExuCel Ag 200 10x20cm
FV000029	ExuCel Ag 200 15x15cm
FV000627	ExuCel Ag 200 15x20cm
FV000628	ExuCel Ag 200 1x30cm
FV000629	ExuCel Ag 200 1x45cm

Product Code /References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FV000630	ExuCel Ag 200 20x20cm
FV000631	ExuCel Ag 200 20x30cm
FV000632	ExuCel Ag 200 2x30cm
FV000030	ExuCel Ag 200 2x45cm
FV000633	ExuCel Ag 200 4x10cm
FV000634	ExuCel Ag 200 4x20cm
FV000635	ExuCel Ag 200 4x30cm
FV000026	ExuCel Ag 200 5x5cm

Model: ExuPro Cel Ag

Concerned medical devices;

Product Code/ References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FV000032	ExuPro Cel Ag 120 10x10cm
FV000033	ExuPro Cel Ag 120 10x12.5cm
FV000636	ExuPro Cel Ag 120 10x12cm
FV000637	ExuPro Cel Ag 120 10x20cm
FV000034	ExuPro Cel Ag 120 15x15cm
FV000638	ExuPro Cel Ag 120 15x20cm
FV000639	ExuPro Cel Ag 120 1x30cm
FV000640	ExuPro Cel Ag 120 1x45cm
FV000641	ExuPro Cel Ag 120 20x20cm
FV000642	ExuPro Cel Ag 120 20x30cm
FV000643	ExuPro Cel Ag 120 2x30cm
FV000035	ExuPro Cel Ag 120 2x45cm
FV000644	ExuPro Cel Ag 120 4x10cm
FV000645	ExuPro Cel Ag 120 4x20cm
FV000646	ExuPro Cel Ag 120 4x30cm
FV000031	ExuPro Cel Ag 120 5x5cm
FV000037	ExuPro Cel Ag 160 10x10cm
FV000038	ExuPro Cel Ag 160 10x12.5cm
FV000647	ExuPro Cel Ag 160 10x12cm
FV000648	ExuPro Cel Ag 160 10x20cm
FV000039	ExuPro Cel Ag 160 15x15cm
FV000649	ExuPro Cel Ag 160 15x20cm
FV000650	ExuPro Cel Ag 160 1x30cm
FV000651	ExuPro Cel Ag 160 1x45cm
FV000652	ExuPro Cel Ag 160 20x20cm
FV000653	ExuPro Cel Ag 160 20x30cm
FV000654	ExuPro Cel Ag 160 2x30cm
FV000040	ExuPro Cel Ag 160 2x45cm
FV000655	ExuPro Cel Ag 160 4x10cm
FV000656	ExuPro Cel Ag 160 4x20cm
FV000657	ExuPro Cel Ag 160 4x30cm
FV000036	ExuPro Cel Ag 160 5x5cm
FV000042	ExuPro Cel Ag 200 10x10cm
FV000043	ExuPro Cel Ag 200 10x12.5cm
FV000658	ExuPro Cel Ag 200 10x12cm
FV000659	ExuPro Cel Ag 200 10x20cm
FV000044	ExuPro Cel Ag 200 15x15cm
FV000660	ExuPro Cel Ag 200 15x20cm
FV000661	ExuPro Cel Ag 200 1x30cm
FV000662	ExuPro Cel Ag 200 1x45cm

Product Code/References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FV000663	ExuPro Cel Ag 200 20x20cm
FV000664	ExuPro Cel Ag 200 20x30cm
FV000665	ExuPro Cel Ag 200 2x30cm
FV000045	ExuPro Cel Ag 200 2x45cm
FV000666	ExuPro Cel Ag 200 4x10cm
FV000667	ExuPro Cel Ag 200 4x20cm
FV000668	ExuPro Cel Ag 200 4x30cm
FV000041	ExuPro Cel Ag 200 5x5cm

Model: Askina Calgitrol Ag+

Concerned medical devices;

Product Code / References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FV000271	Askina® Calgitrol® Ag+ 120 10x10cm
FV000272	Askina® Calgitrol® Ag+ 120 10x12.5cm
FV000276	Askina® Calgitrol® Ag+ 120 10x12cm
FV000283	Askina® Calgitrol® Ag+ 120 10x20cm
FV000273	Askina® Calgitrol® Ag+ 120 15x15cm
FV000284	Askina® Calgitrol® Ag+ 120 15x20cm
FV000281	Askina® Calgitrol® Ag+ 120 1x30cm
FV000282	Askina® Calgitrol® Ag+ 120 1x45cm
FV000285	Askina® Calgitrol® Ag+ 120 20x20cm
FV000275	Askina® Calgitrol® Ag+ 120 20x30cm
FV000280	Askina® Calgitrol® Ag+ 120 2x30cm
FV000274	Askina® Calgitrol® Ag+ 120 2x45cm
FV000277	Askina® Calgitrol® Ag+ 120 4x10cm
FV000278	Askina® Calgitrol® Ag+ 120 4x20cm
FV000279	Askina® Calgitrol® Ag+ 120 4x30cm
FV000270	Askina® Calgitrol® Ag+ 120 5x5cm
FV000287	Askina® Calgitrol® Ag+ 160 10x10cm
FV000288	Askina® Calgitrol® Ag+ 160 10x12.5cm
FV000292	Askina® Calgitrol® Ag+ 160 10x12cm
FV000299	Askina® Calgitrol® Ag+ 160 10x20cm
FV000289	Askina® Calgitrol® Ag+ 160 15x15cm
FV000300	Askina® Calgitrol® Ag+ 160 15x20cm
FV000297	Askina® Calgitrol® Ag+ 160 1x30cm
FV000298	Askina® Calgitrol® Ag+ 160 1x45cm
FV000301	Askina® Calgitrol® Ag+ 160 20x20cm
FV000291	Askina® Calgitrol® Ag+ 160 20x30cm
FV000296	Askina® Calgitrol® Ag+ 160 2x30cm
FV000290	Askina® Calgitrol® Ag+ 160 2x45cm
FV000293	Askina® Calgitrol® Ag+ 160 4x10cm
FV000294	Askina® Calgitrol® Ag+ 160 4x20cm
FV000295	Askina® Calgitrol® Ag+ 160 4x30cm
FV000286	Askina® Calgitrol® Ag+ 160 5x5cm
FV000303	Askina® Calgitrol® Ag+ 200 10x10cm
FV000304	Askina® Calgitrol® Ag+ 200 10x12.5cm
FV000308	Askina® Calgitrol® Ag+ 200 10x12cm
FV000315	Askina® Calgitrol® Ag+ 200 10x20cm
FV000305	Askina® Calgitrol® Ag+ 200 15x15cm
FV000316	Askina® Calgitrol® Ag+ 200 15x20cm
FV000313	Askina® Calgitrol® Ag+ 200 1x30cm
FV000314	Askina® Calgitrol® Ag+ 200 1x45cm

Product Code/References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FV000317	Askina® Calgitrol® Ag+ 200 20x20cm
FV000307	Askina® Calgitrol® Ag+ 200 20x30cm
FV000312	Askina® Calgitrol® Ag+ 200 2x30cm
FV000306	Askina® Calgitrol® Ag+ 200 2x45cm
FV000309	Askina® Calgitrol® Ag+ 200 4x10cm
FV000310	Askina® Calgitrol® Ag+ 200 4x20cm
FV000311	Askina® Calgitrol® Ag+ 200 4x30cm
FV000302	Askina® Calgitrol® Ag+ 200 5x5cm

Model: Advagel Ag

Concerned medical devices;

Product Code / References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FV000167	Advagel Ag 120 10x10cm
FV000168	Advagel Ag 120 10x12.5cm
FV000499	Advagel Ag 120 10x12cm
FV000500	Advagel Ag 120 10x20cm
FV000169	Advagel Ag 120 15x15cm
FV000501	Advagel Ag 120 15x20cm
FV000502	Advagel Ag 120 1x30cm
FV000503	Advagel Ag 120 1x45cm
FV000504	Advagel Ag 120 20x20cm
FV000505	Advagel Ag 120 20x30cm
FV000506	Advagel Ag 120 2x30cm
FV000170	Advagel Ag 120 2x45cm
FV000508	Advagel Ag 120 4x10cm
FV000509	Advagel Ag 120 4x20cm
FV000509	Advagel Ag 120 4x30cm
FV000166	Advagel Ag 120 5x5cm
FV000172	Advagel Ag 160 10x10cm
FV000173	Advagel Ag 160 10x12.5cm
FV000510	Advagel Ag 160 10x12cm
FV000511	Advagel Ag 160 10x20cm
FV000174	Advagel Ag 160 15x15cm
FV000512	Advagel Ag 160 15x20cm
FV000513	Advagel Ag 160 1x30cm
FV000514	Advagel Ag 160 1x45cm
FV000515	Advagel Ag 160 20x20cm
FV000516	Advagel Ag 160 20x30cm
FV000517	Advagel Ag 160 2x30cm
FV000175	Advagel Ag 160 2x45cm
FV000518	Advagel Ag 160 4x10cm
FV000519	Advagel Ag 160 4x20cm
FV000520	Advagel Ag 160 4x30cm
FV000171	Advagel Ag 160 5x5cm
FV000177	Advagel Ag 200 10x10cm
FV000178	Advagel Ag 200 10x12.5cm
FV000521	Advagel Ag 200 10x12cm
FV000522	Advagel Ag 200 10x20cm
FV000179	Advagel Ag 200 15x15cm
FV000523	Advagel Ag 200 15x20cm
FV000524	Advagel Ag 200 1x30cm
FV000525	Advagel Ag 200 1x45cm
FV000526	Advagel Ag 200 20x20cm
FV000527	Advagel Ag 200 20x30cm

Product Code / References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FV000528	Advagel Ag 200 2x30cm
FV000180	Advagel Ag 200 2x45cm
FV000529	Advagel Ag 200 4x10cm
FV000530	Advagel Ag 200 4x20cm
FV000531	Advagel Ag 200 4x30cm
FV000176	Advagel Ag 200 5x5cm

Model: Activheal AquaFiber Ag+ Extra

Concerned medical devices;

Product Code /References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FV000182	ActivHeal Aquafiber Ag + Extra 120 10x10cm
FV000183	ActivHeal Aquafiber Ag + Extra 120 10x12.5cm
FV000466	ActivHeal Aquafiber Ag + Extra 120 10x12cm
FV000467	ActivHeal Aquafiber Ag + Extra 120 10x20cm
FV000184	ActivHeal Aquafiber Ag + Extra 120 15x15cm
FV000468	ActivHeal Aquafiber Ag + Extra 120 15x20cm
FV000469	ActivHeal Aquafiber Ag + Extra 120 1x30cm
FV000470	ActivHeal Aquafiber Ag + Extra 120 1x45cm
FV000471	ActivHeal Aquafiber Ag + Extra 120 20x20cm
FV000472	ActivHeal Aquafiber Ag + Extra 120 20x30cm
FV000473	ActivHeal Aquafiber Ag + Extra 120 2x30cm
FV000185	ActivHeal Aquafiber Ag + Extra 120 2x45cm
FV000474	ActivHeal Aquafiber Ag + Extra 120 4x10cm
FV000475	ActivHeal Aquafiber Ag + Extra 120 4x20cm
FV000476	ActivHeal Aquafiber Ag + Extra 120 4x30cm
FV000181	ActivHeal Aquafiber Ag + Extra 120 5x5cm
FV000187	ActivHeal Aquafiber Ag + Extra 160 10x10cm
FV000188	ActivHeal Aquafiber Ag + Extra 160 10x12.5cm
FV000477	ActivHeal Aquafiber Ag + Extra 160 10x12cm
FV000478	ActivHeal Aquafiber Ag + Extra 160 10x20cm
FV000189	ActivHeal Aquafiber Ag + Extra 160 15x15cm
FV000479	ActivHeal Aquafiber Ag + Extra 160 15x20cm
FV000480	ActivHeal Aquafiber Ag + Extra 160 1x30cm
FV000481	ActivHeal Aquafiber Ag + Extra 160 1x45cm
FV000186	ActivHeal Aquafiber Ag + Extra 160 1x45cm
FV000482	ActivHeal Aquafiber Ag + Extra 160 20x20cm
FV000483	ActivHeal Aquafiber Ag + Extra 160 20x30cm
FV000484	ActivHeal Aquafiber Ag + Extra 160 2x30cm
FV000190	ActivHeal Aquafiber Ag + Extra 160 2x45cm
FV000485	ActivHeal Aquafiber Ag + Extra 160 4x10cm
FV000486	ActivHeal Aquafiber Ag + Extra 160 4x20cm
FV000487	ActivHeal Aquafiber Ag + Extra 160 4x30cm
FV000192	ActivHeal Aquafiber Ag + Extra 200 10x10cm
FV000193	ActivHeal Aquafiber Ag + Extra 200 10x12.5cm
FV000488	ActivHeal Aquafiber Ag + Extra 200 10x12cm
FV000489	ActivHeal Aquafiber Ag + Extra 200 10x20cm
FV000194	ActivHeal Aquafiber Ag + Extra 200 15x15cm
FV000490	ActivHeal Aquafiber Ag + Extra 200 15x20cm
FV000491	ActivHeal Aquafiber Ag + Extra 200 1x30cm
FV000492	ActivHeal Aquafiber Ag + Extra 200 1x45cm

Product Code /References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FV000493	ActivHeal Aquafiber Ag + Extra 200 20x20cm
FV000494	ActivHeal Aquafiber Ag + Extra 200 20x30cm
FV000495	ActivHeal Aquafiber Ag + Extra 200 2x30cm
FV000195	ActivHeal Aquafiber Ag + Extra 200 2x45cm
FV000496	ActivHeal Aquafiber Ag + Extra 200 4x10cm
FV000497	ActivHeal Aquafiber Ag + Extra 200 4x20cm
FV000498	ActivHeal Aquafiber Ag + Extra 200 4x30cm
FV000191	ActivHeal Aquafiber Ag + Extra 200 5x5cm

Model: DuraFiber Ag Pro

Concerned medical devices;

Product Code/References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FV000970	DuraFiber Ag Pro I20 10x10cm
FV000973	DuraFiber Ag Pro I20 10x12.5cm
FV000974	DuraFiber Ag Pro I20 10x12cm
FV000975	DuraFiber Ag Pro I20 10x20cm
FV000976	DuraFiber Ag Pro I20 15x15cm
FV000977	DuraFiber Ag Pro I20 15x20cm
FV000978	DuraFiber Ag Pro I20 1x30cm
FV000979	DuraFiber Ag Pro I20 1x45cm
FV000980	DuraFiber Ag Pro I20 20x20cm
FV000981	DuraFiber Ag Pro I20 20x30cm
FV000982	DuraFiber Ag Pro I20 2x30cm
FV000983	DuraFiber Ag Pro I20 2x45cm
FV000984	DuraFiber Ag Pro I20 4x10cm
FV000985	DuraFiber Ag Pro I20 4x20cm
FV000986	DuraFiber Ag Pro I20 4x30cm
FV000987	DuraFiber Ag Pro I20 5x5cm
FV000971	DuraFiber Ag Pro I60 10x10cm
FV000988	DuraFiber Ag Pro I60 10x12.5cm
FV000989	DuraFiber Ag Pro I60 10x12cm
FV000990	DuraFiber Ag Pro I60 10x20cm
FV000991	DuraFiber Ag Pro I60 15x15cm
FV000992	DuraFiber Ag Pro I60 15x20cm
FV000993	DuraFiber Ag Pro I60 1x30cm
FV000994	DuraFiber Ag Pro I60 1x45cm
FV000995	DuraFiber Ag Pro I60 1x45cm
FV000996	DuraFiber Ag Pro I60 20x20cm
FV000997	DuraFiber Ag Pro I60 20x30cm
FV000998	DuraFiber Ag Pro I60 2x30cm
FV000999	DuraFiber Ag Pro I60 2x45cm
FV00I000	DuraFiber Ag Pro I60 4x10cm
FV00I001	DuraFiber Ag Pro I60 4x20cm
FV00I002	DuraFiber Ag Pro I60 4x30cm
FV000972	DuraFiber Ag Pro 200 10x10cm
FV00I003	DuraFiber Ag Pro 200 10x12.5cm
FV00I004	DuraFiber Ag Pro 200 10x12cm
FV00I005	DuraFiber Ag Pro 200 10x20cm
FV00I006	DuraFiber Ag Pro 200 15x15cm
FV00I007	DuraFiber Ag Pro 200 15x20cm
FV00I008	DuraFiber Ag Pro 200 1x30cm

<u>Product Code / References</u> <u>(codes on DofCs)</u>	<u>Product Variants</u> <u>(Commercial Name / Dimensions)</u>
FV001009	DuraFiber Ag Pro 200 1x45cm
FV001010	DuraFiber Ag Pro 200 20x20cm
FV001011	DuraFiber Ag Pro 200 20x30cm
FV001012	DuraFiber Ag Pro 200 2x30cm
FV001013	DuraFiber Ag Pro 200 2x45cm
FV001014	DuraFiber Ag Pro 200 4x10cm
FV001015	DuraFiber Ag Pro 200 4x20cm
FV001016	DuraFiber Ag Pro 200 4x30cm
FV001017	DuraFiber Ag Pro 200 5x5cm

Model: Celox Burn Dressing

Concerned medical devices;

Product Code / References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FV000212	Celox Burn Dressing 120 10x10cm
FV000213	Celox Burn Dressing 120 10x12.5cm
FV000570	Celox Burn Dressing 120 10x12cm
FV000571	Celox Burn Dressing 120 10x20cm
FV000214	Celox Burn Dressing 120 15x15cm
FV000572	Celox Burn Dressing 120 15x20cm
FV000573	Celox Burn Dressing 120 1x30cm
FV000574	Celox Burn Dressing 120 1x45cm
FV000575	Celox Burn Dressing 120 20x20cm
FV000576	Celox Burn Dressing 120 20x30cm
FV000577	Celox Burn Dressing 120 2x30cm
FV000215	Celox Burn Dressing 120 2x45cm
FV000578	Celox Burn Dressing 120 4x10cm
FV000579	Celox Burn Dressing 120 4x20cm
FV000580	Celox Burn Dressing 120 4x30cm
FV000211	Celox Burn Dressing 120 5x5cm
FV000217	Celox Burn Dressing 160 10x10cm
FV000218	Celox Burn Dressing 160 10x12.5cm
FV000581	Celox Burn Dressing 160 10x12cm
FV000582	Celox Burn Dressing 160 10x20cm
FV000219	Celox Burn Dressing 160 15x15cm
FV000583	Celox Burn Dressing 160 15x20cm
FV000584	Celox Burn Dressing 160 1x30cm
FV000585	Celox Burn Dressing 160 1x45cm
FV000586	Celox Burn Dressing 160 20x20cm
FV000587	Celox Burn Dressing 160 20x30cm
FV000588	Celox Burn Dressing 160 2x30cm
FV000220	Celox Burn Dressing 160 2x45cm
FV000589	Celox Burn Dressing 160 4x10cm
FV000590	Celox Burn Dressing 160 4x20cm
FV000591	Celox Burn Dressing 160 4x30cm
FV000216	Celox Burn Dressing 160 5x5cm
FV000222	Celox Burn Dressing 200 10x10cm
FV000223	Celox Burn Dressing 200 10x12.5cm
FV000592	Celox Burn Dressing 200 10x12cm
FV000593	Celox Burn Dressing 200 10x20cm
FV000224	Celox Burn Dressing 200 15x15cm
FV000594	Celox Burn Dressing 200 15x20cm
FV000595	Celox Burn Dressing 200 1x30cm
FV000596	Celox Burn Dressing 200 1x45cm
FV000597	Celox Burn Dressing 200 20x20cm
FV000598	Celox Burn Dressing 200 20x30cm
FV000599	Celox Burn Dressing 200 2x30cm

Product Code/References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FV000225	Celox Burn Dressing 200 2x45cm
FV000600	Celox Burn Dressing 200 4x10cm
FV000601	Celox Burn Dressing 200 4x20cm
FV000602	Celox Burn Dressing 200 4x30cm
FV000221	Celox Burn Dressing 200 5x5cm

Model: Silvapro Plus

Concerned medical devices;

Product Code / References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FV000227	Silvapro Plus 120 10x10cm
FV000228	Silvapro Plus 120 10x12.5cm
FV000834	Silvapro Plus 120 10x12cm
FV000835	Silvapro Plus 120 10x20cm
FV000229	Silvapro Plus 120 15x15cm
FV000836	Silvapro Plus 120 15x20cm
FV000837	Silvapro Plus 120 1x30cm
FV000838	Silvapro Plus 120 1x45cm
FV000839	Silvapro Plus 120 20x20cm
FV000840	Silvapro Plus 120 20x30cm
FV000841	Silvapro Plus 120 2x30cm
FV000842	Silvapro Plus 120 4x10cm
FV000843	Silvapro Plus 120 4x20cm
FV000844	Silvapro Plus 120 4x30cm
FV000226	Silvapro Plus 120 5x5cm
FV000232	Silvapro Plus 160 10x10cm
FV000233	Silvapro Plus 160 10x12.5cm
FV000845	Silvapro Plus 160 10x12cm
FV000846	Silvapro Plus 160 10x20cm
FV000234	Silvapro Plus 160 15x15cm
FV000847	Silvapro Plus 160 15x20cm
FV000848	Silvapro Plus 160 1x30cm
FV000849	Silvapro Plus 160 1x45cm
FV000850	Silvapro Plus 160 20x20cm
FV000851	Silvapro Plus 160 20x30cm
FV000235	Silvapro Plus 160 2x45cm
FV000852	Silvapro Plus 160 4x10cm
FV000853	Silvapro Plus 160 4x20cm
FV000854	Silvapro Plus 160 4x30cm
FV000231	Silvapro Plus 160 5x5cm
FV000237	Silvapro Plus 200 10x10cm
FV000238	Silvapro Plus 200 10x12.5cm
FV000856	Silvapro Plus 200 10x12cm
FV000857	Silvapro Plus 200 10x20cm
FV000239	Silvapro Plus 200 15x15cm
FV000858	Silvapro Plus 200 15x20cm
FV000859	Silvapro Plus 200 1x30cm
FV000860	Silvapro Plus 200 1x45cm
FV000861	Silvapro Plus 200 20x20cm
FV000862	Silvapro Plus 200 20x30cm
FV000863	Silvapro Plus 200 2x30cm
FV000240	Silvapro Plus 200 2x45cm
FV000864	Silvapro Plus 200 4x10cm
FV000865	Silvapro Plus 200 4x20cm
FV000866	Silvapro Plus 200 4x30cm

Product Code / References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FV000236	Silvapro Plus 200 5x5cm
FV000230	Silvapro Plus120 2x45cm
FV000855	Silvapro Plus160 2x30cm

Model: Suprasorb Liquacel Ag

Concerned medical devices;

Product Code /References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FV000242	Suprasorb Liquacel Ag 120 10x10cm
FV000243	Suprasorb Liquacel Ag 120 10x12.5cm
FV000867	Suprasorb Liquacel Ag 120 10x12cm
FV000868	Suprasorb Liquacel Ag 120 10x20cm
FV000244	Suprasorb Liquacel Ag 120 15x15cm
FV000869	Suprasorb Liquacel Ag 120 15x20cm
FV000870	Suprasorb Liquacel Ag 120 1x30cm
FV000871	Suprasorb Liquacel Ag 120 1x45cm
FV000872	Suprasorb Liquacel Ag 120 20x20cm
FV000873	Suprasorb Liquacel Ag 120 20x30cm
FV000874	Suprasorb Liquacel Ag 120 2x30cm
FV000245	Suprasorb Liquacel Ag 120 2x45cm
FV000261	Suprasorb Liquacel Ag 120 4x10cm
FV000267	Suprasorb Liquacel Ag 120 4x20cm
FV000268	Suprasorb Liquacel Ag 120 4x30cm
FV000241	Suprasorb Liquacel Ag 120 5x5cm
FV000247	Suprasorb Liquacel Ag 160 10x10cm
FV000248	Suprasorb Liquacel Ag 160 10x12.5cm
FV000269	Suprasorb Liquacel Ag 160 10x12cm
FV000318	Suprasorb Liquacel Ag 160 10x20cm
FV000249	Suprasorb Liquacel Ag 160 15x15cm
FV000319	Suprasorb Liquacel Ag 160 15x20cm
FV000320	Suprasorb Liquacel Ag 160 1x30cm
FV000321	Suprasorb Liquacel Ag 160 1x45cm
FV000322	Suprasorb Liquacel Ag 160 20x20cm
FV000264	Suprasorb Liquacel Ag 160 20x30cm
FV000875	Suprasorb Liquacel Ag 160 2x30cm
FV000250	Suprasorb Liquacel Ag 160 2x45cm
FV000263	Suprasorb Liquacel Ag 160 4x10cm
FV000876	Suprasorb Liquacel Ag 160 4x20cm
FV000877	Suprasorb Liquacel Ag 160 4x30cm
FV000246	Suprasorb Liquacel Ag 160 5x5cm
FV000252	Suprasorb Liquacel Ag 200 10x10cm
FV000253	Suprasorb Liquacel Ag 200 10x12.5cm
FV000878	Suprasorb Liquacel Ag 200 10x12cm
FV000879	Suprasorb Liquacel Ag 200 10x20cm
FV000254	Suprasorb Liquacel Ag 200 15x15cm
FV000880	Suprasorb Liquacel Ag 200 15x20cm
FV000881	Suprasorb Liquacel Ag 200 1x30cm

Product Code/References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FV000882	Suprasorb Liquacel Ag 200 1x45cm
FV000883	Suprasorb Liquacel Ag 200 20x20cm
FV000266	Suprasorb Liquacel Ag 200 20x30cm
FV000884	Suprasorb Liquacel Ag 200 2x30cm
FV000255	Suprasorb Liquacel Ag 200 2x45cm
FV000265	Suprasorb Liquacel Ag 200 4x10cm
FV000885	Suprasorb Liquacel Ag 200 4x20cm
FV000886	Suprasorb Liquacel Ag 200 4x30cm
FV000251	Suprasorb Liquacel Ag 200 5x5cm

Model: LunaFiber Ag

Concerned medical devices;

Product Codes/References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FV000062	LunaFiber Ag 120 10x10cm
FV000063	LunaFiber Ag 120 10x12.5cm
FV000669	LunaFiber Ag 120 10x12cm
FV000670	LunaFiber Ag 120 10x20cm
FV000064	LunaFiber Ag 120 15x15cm
FV000671	LunaFiber Ag 120 15x20cm
FV000672	LunaFiber Ag 120 1x30cm
FV000673	LunaFiber Ag 120 1x45cm
FV000674	LunaFiber Ag 120 20x20cm
FV000675	LunaFiber Ag 120 20x30cm
FV000676	LunaFiber Ag 120 2x30cm
FV000065	LunaFiber Ag 120 2x45cm
FV000677	LunaFiber Ag 120 4x10cm
FV000678	LunaFiber Ag 120 4x20cm
FV000679	LunaFiber Ag 120 4x30cm
FV000061	LunaFiber Ag 120 5x5cm
FV000067	LunaFiber Ag 160 10x10cm
FV000068	LunaFiber Ag 160 10x12.5cm
FV000680	LunaFiber Ag 160 10x12cm
FV000681	LunaFiber Ag 160 10x20cm
FV000069	LunaFiber Ag 160 15x15cm
FV000682	LunaFiber Ag 160 15x20cm
FV000683	LunaFiber Ag 160 1x30cm
FV000684	LunaFiber Ag 160 1x45cm
FV000685	LunaFiber Ag 160 20x20cm
FV000686	LunaFiber Ag 160 20x30cm
FV000687	LunaFiber Ag 160 2x30cm
FV000070	LunaFiber Ag 160 2x45cm
FV000688	LunaFiber Ag 160 4x10cm
FV000689	LunaFiber Ag 160 4x20cm
FV000690	LunaFiber Ag 160 4x30cm
FV000066	LunaFiber Ag 160 5x5cm
FV000072	LunaFiber Ag 200 10x10cm
FV000073	LunaFiber Ag 200 10x12.5cm
FV000691	LunaFiber Ag 200 10x12cm
FV000692	LunaFiber Ag 200 10x20cm
FV000074	LunaFiber Ag 200 15x15cm
FV000693	LunaFiber Ag 200 15x20cm
FV000694	LunaFiber Ag 200 1x30cm
FV000695	LunaFiber Ag 200 1x45cm
FV000696	LunaFiber Ag 200 20x20cm

Product Codes/References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FV000697	LunaFiber Ag 200 20x30cm
FV000698	LunaFiber Ag 200 2x30cm
FV000075	LunaFiber Ag 200 2x45cm
FV000699	LunaFiber Ag 200 4x10cm
FV000700	LunaFiber Ag 200 4x20cm
FV000701	LunaFiber Ag 200 4x30cm
FV000071	LunaFiber Ag 200 5x5cm

Amendment Kiwa MY-23-002511 Appendix 2

Product: Pluto Ag

Model: AlgiPro Ultima Ag

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FT650380	AlgiPro Ultima Ag 120 10x10cm
FT650379	AlgiPro Ultima Ag 120 10x12.5cm
FT650381	AlgiPro Ultima Ag 120 10x12cm
FT650378	AlgiPro Ultima Ag 120 10x20cm
FT650377	AlgiPro Ultima Ag 120 15x15cm
FT650376	AlgiPro Ultima Ag 120 15x20cm
FT650385	AlgiPro Ultima Ag 120 1x30cm
FT650386	AlgiPro Ultima Ag 120 1x45cm
FT650387	AlgiPro Ultima Ag 120 20x20cm
FT650375	AlgiPro Ultima Ag 120 20x30cm
FT650374	AlgiPro Ultima Ag 120 2x30cm
FT650373	AlgiPro Ultima Ag 120 2x45cm
FT650382	AlgiPro Ultima Ag 120 4x10cm
FT650383	AlgiPro Ultima Ag 120 4x20cm
FT650384	AlgiPro Ultima Ag 120 4x30cm
FT650372	AlgiPro Ultima Ag 120 5x5cm
FT650396	AlgiPro Ultima Ag 200 10x10cm
FT650395	AlgiPro Ultima Ag 200 10x12.5cm
FT650397	AlgiPro Ultima Ag 200 10x12cm
FT650394	AlgiPro Ultima Ag 200 10x20cm
FT650393	AlgiPro Ultima Ag 200 15x15cm
FT650392	AlgiPro Ultima Ag 200 15x20cm
FT650401	AlgiPro Ultima Ag 200 1x30cm
FT650402	AlgiPro Ultima Ag 200 1x45cm
FT650403	AlgiPro Ultima Ag 200 20x20cm
FT650391	AlgiPro Ultima Ag 200 20x30cm
FT650390	AlgiPro Ultima Ag 200 2x30cm
FT650389	AlgiPro Ultima Ag 200 2x45cm
FT650398	AlgiPro Ultima Ag 200 4x10cm
FT650399	AlgiPro Ultima Ag 200 4x20cm
FT650400	AlgiPro Ultima Ag 200 4x30cm

<u>Product Codes / References</u> (codes on DofCs)	<u>Product Variants</u> (Commercial Name / Dimensions)
FT650388	AlgiPro Ultima Ag 200 5x5cm

Model: Algipure Ag Plus

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FT650412	Algipure AG Plus 120 10x10cm
FT650411	Algipure AG Plus 120 10x12.5cm
FT650413	Algipure AG Plus 120 10x12cm
FT650410	Algipure AG Plus 120 10x20cm
FT650409	Algipure AG Plus 120 15x15cm
FT650408	Algipure AG Plus 120 15x20cm
FT650417	Algipure AG Plus 120 1x30cm
FT650418	Algipure AG Plus 120 1x45cm
FT650419	Algipure AG Plus 120 20x20cm
FT650407	Algipure AG Plus 120 20x30cm
FT650406	Algipure AG Plus 120 2x30cm
FT650405	Algipure AG Plus 120 2x45cm
FT650414	Algipure AG Plus 120 4x10cm
FT650415	Algipure AG Plus 120 4x20cm
FT650416	Algipure AG Plus 120 4x30cm
FT650404	Algipure AG Plus 120 5x5cm
FT650428	Algipure AG Plus 200 10x10cm
FT650427	Algipure AG Plus 200 10x12.5cm
FT650429	Algipure AG Plus 200 10x12cm
FT650426	Algipure AG Plus 200 10x20cm
FT650425	Algipure AG Plus 200 15x15cm
FT650424	Algipure AG Plus 200 15x20cm
FT650433	Algipure AG Plus 200 1x30cm
FT650434	Algipure AG Plus 200 1x45cm
FT650435	Algipure AG Plus 200 20x20cm
FT650423	Algipure AG Plus 200 20x30cm
FT650422	Algipure AG Plus 200 2x30cm
FT650421	Algipure AG Plus 200 2x45cm
FT650430	Algipure AG Plus 200 4x10cm
FT650431	Algipure AG Plus 200 4x20cm
FT650432	Algipure AG Plus 200 4x30cm
FT650420	Algipure AG Plus 200 5x5cm

Model: AlgiWound Ultima Ag

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FT650444	AlgiWound Ultima Ag 120 10x10cm
FT650443	AlgiWound Ultima Ag 120 10x12.5cm
FT650445	AlgiWound Ultima Ag 120 10x12cm
FT650442	AlgiWound Ultima Ag 120 10x20cm
FT650441	AlgiWound Ultima Ag 120 15x15cm
FT650440	AlgiWound Ultima Ag 120 15x20cm
FT650449	AlgiWound Ultima Ag 120 1x30cm
FT650450	AlgiWound Ultima Ag 120 1x45cm
FT650451	AlgiWound Ultima Ag 120 20x20cm
FT650439	AlgiWound Ultima Ag 120 20x30cm
FT650438	AlgiWound Ultima Ag 120 2x30cm
FT650437	AlgiWound Ultima Ag 120 2x45cm
FT650446	AlgiWound Ultima Ag 120 4x10cm
FT650447	AlgiWound Ultima Ag 120 4x20cm
FT650448	AlgiWound Ultima Ag 120 4x30cm
FT650436	AlgiWound Ultima Ag 120 5x5cm
FT650460	AlgiWound Ultima Ag 200 10x10cm
FT650459	AlgiWound Ultima Ag 200 10x12.5cm
FT650461	AlgiWound Ultima Ag 200 10x12cm
FT650458	AlgiWound Ultima Ag 200 10x20cm
FT650457	AlgiWound Ultima Ag 200 15x15cm
FT650456	AlgiWound Ultima Ag 200 15x20cm
FT650466	AlgiWound Ultima Ag 200 1x30cm
FT650467	AlgiWound Ultima Ag 200 1x45cm
FT650468	AlgiWound Ultima Ag 200 20x20cm
FT650455	AlgiWound Ultima Ag 200 20x30cm
FT650454	AlgiWound Ultima Ag 200 2x30cm
FT650453	AlgiWound Ultima Ag 200 2x45cm
FT650463	AlgiWound Ultima Ag 200 4x10cm
FT650464	AlgiWound Ultima Ag 200 4x20cm
FT650465	AlgiWound Ultima Ag 200 4x30cm
FT650452	AlgiWound Ultima Ag 200 5x5cm

Model: CovaWound Alginate Ag+

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FT650477	CovaWound Alginate Ag+ 120 10x10cm
FT650476	CovaWound Alginate Ag+ 120 10x12.5cm
FT650478	CovaWound Alginate Ag+ 120 10x12cm
FT650475	CovaWound Alginate Ag+ 120 10x20cm
FT650474	CovaWound Alginate Ag+ 120 15x15cm
FT650473	CovaWound Alginate Ag+ 120 15x20cm
FT650482	CovaWound Alginate Ag+ 120 1x30cm
FT650483	CovaWound Alginate Ag+ 120 1x45cm
FT650484	CovaWound Alginate Ag+ 120 20x20cm
FT650472	CovaWound Alginate Ag+ 120 20x30cm
FT650471	CovaWound Alginate Ag+ 120 2x30cm
FT650470	CovaWound Alginate Ag+ 120 2x45cm
FT650479	CovaWound Alginate Ag+ 120 4x10cm
FT650480	CovaWound Alginate Ag+ 120 4x20cm
FT650481	CovaWound Alginate Ag+ 120 4x30cm
FT650469	CovaWound Alginate Ag+ 120 5x5cm
FT650493	CovaWound Alginate Ag+ 200 10x10cm
FT650492	CovaWound Alginate Ag+ 200 10x12.5cm
FT650494	CovaWound Alginate Ag+ 200 10x12cm
FT650491	CovaWound Alginate Ag+ 200 10x20cm
FT650490	CovaWound Alginate Ag+ 200 15x15cm
FT650489	CovaWound Alginate Ag+ 200 15x20cm
FT650498	CovaWound Alginate Ag+ 200 1x30cm
FT650499	CovaWound Alginate Ag+ 200 1x45cm
FT650500	CovaWound Alginate Ag+ 200 20x20cm
FT650488	CovaWound Alginate Ag+ 200 20x30cm
FT650487	CovaWound Alginate Ag+ 200 2x30cm
FT650486	CovaWound Alginate Ag+ 200 2x45cm
FT650495	CovaWound Alginate Ag+ 200 4x10cm
FT650496	CovaWound Alginate Ag+ 200 4x20cm
FT650485	CovaWound Alginate Ag+ 200 5x5cm
FT650497	CovaWound Alginate Ag+ Ag 200 4x30cm

Model: ExuPro Advance Ag

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FT000890	ExuPro Advance Ag 120 10x10cm
FT000892	ExuPro Advance Ag 120 10x12.5cm
FT000891	ExuPro Advance Ag 120 10x12cm
FT000893	ExuPro Advance Ag 120 10x20cm
FT000897	ExuPro Advance Ag 120 15x15cm
FT000898	ExuPro Advance Ag 120 15x20cm
FT000894	ExuPro Advance Ag 120 1x30cm
FT000895	ExuPro Advance Ag 120 1x45cm
FT000896	ExuPro Advance Ag 120 20x20cm
FT000899	ExuPro Advance Ag 120 20x30cm
FT000900	ExuPro Advance Ag 120 2x30cm
FT000901	ExuPro Advance Ag 120 2x45cm
FT000902	ExuPro Advance Ag 120 4x10cm
FT000903	ExuPro Advance Ag 120 4x20cm
FT000904	ExuPro Advance Ag 120 4x30cm
FT000905	ExuPro Advance Ag 120 5x5cm
FT000906	ExuPro Advance Ag 200 10x10cm
FT000910	ExuPro Advance Ag 200 10x12.5cm
FT000907	ExuPro Advance Ag 200 10x12cm
FT000908	ExuPro Advance Ag 200 10x20cm
FT000913	ExuPro Advance Ag 200 15x15cm
FT000914	ExuPro Advance Ag 200 15x20cm
FT000909	ExuPro Advance Ag 200 1x30cm
FT000911	ExuPro Advance Ag 200 1x45cm
FT000912	ExuPro Advance Ag 200 20x20cm
FT000915	ExuPro Advance Ag 200 20x30cm
FT000916	ExuPro Advance Ag 200 2x30cm
FT000917	ExuPro Advance Ag 200 2x45cm
FT000918	ExuPro Advance Ag 200 4x10cm
FT000919	ExuPro Advance Ag 200 4x20cm
FT000920	ExuPro Advance Ag 200 4x30cm
FT000921	ExuPro Advance Ag 200 5x5cm

Model: Pluto Ag

Concerned medical devices;

Product Codes / References (codes on DoFCs)	Product Variants (Commercial Name/ Dimensions)
FT650516	Pluto Ag 120 10x10cm
FT650514	Pluto Ag 120 10x12.5cm
FT650515	Pluto Ag 120 10x12cm
FT650513	Pluto Ag 120 10x20cm
FT650509	Pluto Ag 120 15x15cm
FT650508	Pluto Ag 120 15x20cm
FT650512	Pluto Ag 120 1x30cm
FT650510	Pluto Ag 120 1x45cm
FT650511	Pluto Ag 120 20x20cm
FT650507	Pluto Ag 120 20x30cm
FT650506	Pluto Ag 120 2x30cm
FT650505	Pluto Ag 120 2x45cm
FT650504	Pluto Ag 120 4x10cm
FT650503	Pluto Ag 120 4x20cm
FT650502	Pluto Ag 120 4x30cm
FT650501	Pluto Ag 120 5x5cm
FT650532	Pluto Ag 200 10x10cm
FT650530	Pluto Ag 200 10x12.5cm
FT650531	Pluto Ag 200 10x12cm
FT650529	Pluto Ag 200 10x20cm
FT650525	Pluto Ag 200 15x15cm
FT650524	Pluto Ag 200 15x20cm
FT650528	Pluto Ag 200 1x30cm
FT650526	Pluto Ag 200 1x45cm
FT650527	Pluto Ag 200 20x20cm
FT650523	Pluto Ag 200 20x30cm
FT650522	Pluto Ag 200 2x30cm
FT650521	Pluto Ag 200 2x45cm
FT650520	Pluto Ag 200 4x10cm
FT650519	Pluto Ag 200 4x20cm
FT650518	Pluto Ag 200 4x30cm
FT650517	Pluto Ag 200 5x5cm

Model: SelectWound Pro Ag

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FT650541	SelectWound Pro Ag 120 10x10cm
FT650540	SelectWound Pro Ag 120 10x12.5cm
FT650542	SelectWound Pro Ag 120 10x12cm
FT650539	SelectWound Pro Ag 120 10x20cm
FT650538	SelectWound Pro Ag 120 15x15cm
FT650537	SelectWound Pro Ag 120 15x20cm
FT650546	SelectWound Pro Ag 120 1x30cm
FT650547	SelectWound Pro Ag 120 1x45cm
FT650548	SelectWound Pro Ag 120 20x20cm
FT650536	SelectWound Pro Ag 120 20x30cm
FT650535	SelectWound Pro Ag 120 2x30cm
FT650534	SelectWound Pro Ag 120 2x45cm
FT650543	SelectWound Pro Ag 120 4x10cm
FT650544	SelectWound Pro Ag 120 4x20cm
FT650545	SelectWound Pro Ag 120 4x30cm
FT650533	SelectWound Pro Ag 120 5x5cm
FT650557	SelectWound Pro Ag 200 10x10cm
FT650556	SelectWound Pro Ag 200 10x12.5cm
FT650558	SelectWound Pro Ag 200 10x12cm
FT650555	SelectWound Pro Ag 200 10x20cm
FT650554	SelectWound Pro Ag 200 15x15cm
FT650553	SelectWound Pro Ag 200 15x20cm
FT650561	SelectWound Pro Ag 200 1x30cm
FT650562	SelectWound Pro Ag 200 1x45cm
FT650563	SelectWound Pro Ag 200 20x20cm
FT650552	SelectWound Pro Ag 200 20x30cm
FT650551	SelectWound Pro Ag 200 2x30cm
FT650550	SelectWound Pro Ag 200 2x45cm
FT650559	SelectWound Pro Ag 200 4x10cm
FT650560	SelectWound Pro Ag 200 4x20cm
FT650661	SelectWound Pro Ag 200 4x30cm
FT650549	SelectWound Pro Ag 200 5x5cm

Model: SelectWound Ultima Ag

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FT650572	SelectWound Ultima Ag 120 10x10cm
FT650571	SelectWound Ultima Ag 120 10x12.5cm
FT650573	SelectWound Ultima Ag 120 10x12cm
FT650570	SelectWound Ultima Ag 120 10x20cm
FT650569	SelectWound Ultima Ag 120 15x15cm
FT650566	SelectWound Ultima Ag 120 15x20cm
FT650577	SelectWound Ultima Ag 120 1x30cm
FT650578	SelectWound Ultima Ag 120 1x45cm
FT650579	SelectWound Ultima Ag 120 20x20cm
FT650567	SelectWound Ultima Ag 120 20x30cm
FT650566	SelectWound Ultima Ag 120 2x30cm
FT650565	SelectWound Ultima Ag 120 2x45cm
FT650574	SelectWound Ultima Ag 120 4x10cm
FT650575	SelectWound Ultima Ag 120 4x20cm
FT650576	SelectWound Ultima Ag 120 4x30cm
FT650572	SelectWound Ultima Ag 120 5x5cm
FT650588	SelectWound Ultima Ag 200 10x10cm
FT650587	SelectWound Ultima Ag 200 10x12.5cm
FT650589	SelectWound Ultima Ag 200 10x12cm
FT650586	SelectWound Ultima Ag 200 10x20cm
FT650593	SelectWound Ultima Ag 200 1x30cm
FT650594	SelectWound Ultima Ag 200 1x45cm
FT650595	SelectWound Ultima Ag 200 20x20cm
FT650590	SelectWound Ultima Ag 200 4x10cm
FT650591	SelectWound Ultima Ag 200 4x20cm
FT650592	SelectWound Ultima Ag 200 4x30cm
FT650580	SelectWound Ultima Ag 200 5x5cm
FT650585	SelectWound Ultima Ag 200, 15x15cm
FT650584	SelectWound Ultima Ag 200, 15x20cm
FT650583	SelectWound Ultima Ag 200, 20x30cm
FT650582	SelectWound Ultima Ag 200, 2x30cm
FT650581	SelectWound Ultima Ag 200, 2x45cm

Model: Suprasorb A+Ag Pro

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
PLUAG1010120	Suprasorb A+Ag Pro 120 10x10cm
FT650602	Suprasorb A+Ag Pro 120 10x12.5cm
FT650604	Suprasorb A+Ag Pro 120 10x12cm
PLUAG1020120	Suprasorb A+Ag Pro 120 10x20cm
FT650600	Suprasorb A+Ag Pro 120 15x15cm
FT650599	Suprasorb A+Ag Pro 120 15x20cm
FT650607	Suprasorb A+Ag Pro 120 1x30cm
FT650608	Suprasorb A+Ag Pro 120 1x45cm
FT650609	Suprasorb A+Ag Pro 120 20x20cm
FT650109	Suprasorb A+Ag Pro 120 20x30cm
FT650598	Suprasorb A+Ag Pro 120 2x30cm
PLUAG245120	Suprasorb A+Ag Pro 120 2x45cm
FT650108	Suprasorb A+Ag Pro 120 4x10cm
FT650605	Suprasorb A+Ag Pro 120 4x20cm
FT650606	Suprasorb A+Ag Pro 120 4x30cm
PLUAG55120	Suprasorb A+Ag Pro 120 5x5cm
FT650617	Suprasorb A+Ag Pro 200 10x10cm
FT650616	Suprasorb A+Ag Pro 200 10x12.5cm
FT650618	Suprasorb A+Ag Pro 200 10x12cm
FT650615	Suprasorb A+Ag Pro 200 10x20cm
FT650614	Suprasorb A+Ag Pro 200 15x15cm
FT650613	Suprasorb A+Ag Pro 200 15x20cm
FT650621	Suprasorb A+Ag Pro 200 1x30cm
FT650622	Suprasorb A+Ag Pro 200 1x45cm
FT650623	Suprasorb A+Ag Pro 200 20x20cm
FT650111	Suprasorb A+Ag Pro 200 20x30cm
FT650612	Suprasorb A+Ag Pro 200 2x30cm
FT650611	Suprasorb A+Ag Pro 200 2x45cm
FT650110	Suprasorb A+Ag Pro 200 4x10cm
FT650619	Suprasorb A+Ag Pro 200 4x20cm
FT650620	Suprasorb A+Ag Pro 200 4x30cm
FT650610	Suprasorb A+Ag Pro 200 5x5cm

Amendment Kiwa MY-23-002511 Appendix 3

Product: Silver Alginate

Model: AlgiPro Ag

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FAI70640	AlgiPro Ag AgLI30 10x10cm
FAI70648	AlgiPro Ag AgLI30 10x12.5cm
FAI70699	AlgiPro Ag AgLI30 10x12cm
FAI70656	AlgiPro Ag AgLI30 10x20cm
FAI70664	AlgiPro Ag AgLI30 15x15cm
FAI70672	AlgiPro Ag AgLI30 15x20cm
FAI70703	AlgiPro Ag AgLI30 1x30cm
FAI70704	AlgiPro Ag AgLI30 1x45cm
FAI70705	AlgiPro Ag AgLI30 20x20cm
FAI70680	AlgiPro Ag AgLI30 20x30cm
FAI70697	AlgiPro Ag AgLI30 2x30cm
FAI70698	AlgiPro Ag AgLI30 2x45cm
FAI70700	AlgiPro Ag AgLI30 4x10cm
FAI70701	AlgiPro Ag AgLI30 4x20cm
FAI70702	AlgiPro Ag AgLI30 4x30cm
FAI70689	AlgiPro Ag AgLI30 5x5cm
FAI70707	AlgiPro Ag AgW330 10x10cm
FAI70708	AlgiPro Ag AgW330 10x12.5cm
FAI70713	AlgiPro Ag AgW330 10x12cm
FAI70709	AlgiPro Ag AgW330 10x20cm
FAI70710	AlgiPro Ag AgW330 15x15cm
FAI70711	AlgiPro Ag AgW330 15x20cm
FAI70718	AlgiPro Ag AgW330 1x30cm
FAI70719	AlgiPro Ag AgW330 1x45cm
FAI70714	AlgiPro Ag AgW330 20x20cm
FAI70712	AlgiPro Ag AgW330 20x30cm
FAI70618	AlgiPro Ag AgW330 2x30cm
FAI70630	AlgiPro Ag AgW330 2x45cm
FAI70715	AlgiPro Ag AgW330 4x10cm
FAI70716	AlgiPro Ag AgW330 4x20cm
FAI70717	AlgiPro Ag AgW330 4x30cm
FAI70706	AlgiPro Ag AgW330 5x5cm

Model: Algipure AG

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FAI70641	Algipure AG AgLI30 10x10cm
FAI70649	Algipure AG AgLI30 10x12.5cm
FAI70722	Algipure AG AgLI30 10x12cm
FAI70657	Algipure AG AgLI30 10x20cm
FAI70665	Algipure AG AgLI30 15x15cm
FAI70673	Algipure AG AgLI30 15x20cm
FAI70726	Algipure AG AgLI30 1x30cm
FAI70727	Algipure AG AgLI30 1x45cm
FAI70728	Algipure AG AgLI30 20x20cm
FAI70681	Algipure AG AgLI30 20x30cm
FAI70720	Algipure AG AgLI30 2x30cm
FAI70721	Algipure AG AgLI30 2x45cm
FAI70723	Algipure AG AgLI30 4x10cm
FAI70724	Algipure AG AgLI30 4x20cm
FAI70725	Algipure AG AgLI30 4x30cm
FAI70690	Algipure AG AgLI30 5x5cm
FAI70730	Algipure AG AgW330 10x10cm
FAI70731	Algipure AG AgW330 10x12.5cm
FAI70736	Algipure AG AgW330 10x12cm
FAI70732	Algipure AG AgW330 10x20cm
FAI70733	Algipure AG AgW330 15x15cm
FAI70734	Algipure AG AgW330 15x20cm
FAI70741	Algipure AG AgW330 1x30cm
FAI70742	Algipure AG AgW330 1x45cm
FAI70737	Algipure AG AgW330 20x20cm
FAI70735	Algipure AG AgW330 20x30cm
FAI70619	Algipure AG AgW330 2x30cm
FAI70631	Algipure AG AgW330 2x45cm
FAI70738	Algipure AG AgW330 4x10cm
FAI70739	Algipure AG AgW330 4x20cm
FAI70740	Algipure AG AgW330 4x30cm
FAI70729	Algipure AG AgW330 5x5cm

Model: AlgiWound Ag

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FAI70642	AlgiWound Ag AgLI30 10x10cm
FAI70650	AlgiWound Ag AgLI30 10x12.5cm
FAI70745	AlgiWound Ag AgLI30 10x12cm
FAI70658	AlgiWound Ag AgLI30 10x20cm
FAI70666	AlgiWound Ag AgLI30 15x15cm
FAI70674	AlgiWound Ag AgLI30 15x20cm
FAI70749	AlgiWound Ag AgLI30 1x30cm
FAI70750	AlgiWound Ag AgLI30 1x45cm
FAI70751	AlgiWound Ag AgLI30 20x20cm
FAI70682	AlgiWound Ag AgLI30 20x30cm
FAI70743	AlgiWound Ag AgLI30 2x30cm
FAI70744	AlgiWound Ag AgLI30 2x45cm
FAI70746	AlgiWound Ag AgLI30 4x10cm
FAI70747	AlgiWound Ag AgLI30 4x20cm
FAI70748	AlgiWound Ag AgLI30 4x30cm
FAI70691	AlgiWound Ag AgLI30 5x5cm
FAI70753	AlgiWound Ag AgW330 10x10cm
FAI70754	AlgiWound Ag AgW330 10x12.5cm
FAI70759	AlgiWound Ag AgW330 10x12cm
FAI70755	AlgiWound Ag AgW330 10x20cm
FAI70756	AlgiWound Ag AgW330 15x15cm
FAI70757	AlgiWound Ag AgW330 15x20cm
FAI70764	AlgiWound Ag AgW330 1x30cm
FAI70765	AlgiWound Ag AgW330 1x45cm
FAI70760	AlgiWound Ag AgW330 20x20cm
FAI70758	AlgiWound Ag AgW330 20x30cm
FAI70624	AlgiWound Ag AgW330 2x30cm
FAI70632	AlgiWound Ag AgW330 2x45cm
FAI70761	AlgiWound Ag AgW330 4x10cm
FAI70762	AlgiWound Ag AgW330 4x20cm
FAI70763	AlgiWound Ag AgW330 4x30cm
FAI70752	AlgiWound Ag AgW330 5x5cm

Model: CovaWound Alginate Ag

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FAI70643	CovaWound Alginate Ag AgL130 10x10cm
FAI70651	CovaWound Alginate Ag AgL130 10x12.5cm
FAI70768	CovaWound Alginate Ag AgL130 10x12cm
FAI70659	CovaWound Alginate Ag AgL130 10x20cm
FAI70667	CovaWound Alginate Ag AgL130 15x15cm
FAI70675	CovaWound Alginate Ag AgL130 15x20cm
FAI70773	CovaWound Alginate Ag AgL130 1x30cm
FAI70774	CovaWound Alginate Ag AgL130 1x45cm
FAI70775	CovaWound Alginate Ag AgL130 20x20cm
FAI70683	CovaWound Alginate Ag AgL130 20x30cm
FAI70766	CovaWound Alginate Ag AgL130 2x30cm
FAI70767	CovaWound Alginate Ag AgL130 2x45cm
FAI70769	CovaWound Alginate Ag AgL130 4x10cm
FAI70770	CovaWound Alginate Ag AgL130 4x20cm
FAI70772	CovaWound Alginate Ag AgL130 4x30cm
FAI70692	CovaWound Alginate Ag AgL130 5x5cm
FAI70777	CovaWound Alginate Ag AgW330 10x10cm
FAI70778	CovaWound Alginate Ag AgW330 10x12.5cm
FAI70783	CovaWound Alginate Ag AgW330 10x12cm
FAI70779	CovaWound Alginate Ag AgW330 10x20cm
FAI70780	CovaWound Alginate Ag AgW330 15x15cm
FAI70781	CovaWound Alginate Ag AgW330 15x20cm
FAI70788	CovaWound Alginate Ag AgW330 1x30cm
FAI70789	CovaWound Alginate Ag AgW330 1x45cm
FAI70784	CovaWound Alginate Ag AgW330 20x20cm
FAI70782	CovaWound Alginate Ag AgW330 20x30cm
FAI70625	CovaWound Alginate Ag AgW330 2x30cm
FAI70633	CovaWound Alginate Ag AgW330 2x45cm
FAI70785	CovaWound Alginate Ag AgW330 4x10cm
FAI70786	CovaWound Alginate Ag AgW330 4x20cm
FAI70787	CovaWound Alginate Ag AgW330 4x30cm
FAI70776	CovaWound Alginate Ag AgW330 5x5cm

Model: ExuPro Ag

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name / Dimensions)
FAI70644	ExuPro Ag AgLI30 10x10cm
FAI70652	ExuPro Ag AgLI30 10x12.5cm
FAI70792	ExuPro Ag AgLI30 10x12cm
FAI70660	ExuPro Ag AgLI30 10x20cm
FAI70668	ExuPro Ag AgLI30 15x15cm
FAI70676	ExuPro Ag AgLI30 15x20cm
FAI70796	ExuPro Ag AgLI30 1x30cm
FAI70797	ExuPro Ag AgLI30 1x45cm
FAI70798	ExuPro Ag AgLI30 20x20cm
FAI70684	ExuPro Ag AgLI30 20x30cm
FAI70790	ExuPro Ag AgLI30 2x30cm
FAI70791	ExuPro Ag AgLI30 2x45cm
FAI70793	ExuPro Ag AgLI30 4x10cm
FAI70794	ExuPro Ag AgLI30 4x20cm
FAI70795	ExuPro Ag AgLI30 4x30cm
FAI70693	ExuPro Ag AgLI30 5x5cm
FAI70800	ExuPro Ag AgW330 10x10cm
FAI70801	ExuPro Ag AgW330 10x12.5cm
FAI70806	ExuPro Ag AgW330 10x12cm
FAI70802	ExuPro Ag AgW330 10x20cm
FAI70803	ExuPro Ag AgW330 15x15cm
FAI70804	ExuPro Ag AgW330 15x20cm
FAI70811	ExuPro Ag AgW330 1x30cm
FAI70812	ExuPro Ag AgW330 1x45cm
FAI70807	ExuPro Ag AgW330 20x20cm
FAI70805	ExuPro Ag AgW330 20x30cm
FAI70626	ExuPro Ag AgW330 2x30cm
FAI70634	ExuPro Ag AgW330 2x45cm
FAI70808	ExuPro Ag AgW330 4x10cm
FAI70809	ExuPro Ag AgW330 4x20cm
FAI70810	ExuPro Ag AgW330 4x30cm
FAI70799	ExuPro Ag AgW330 5x5cm

Model: SelectWound Ag

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FAI70645	SelectWound Ag AgLI30 10x10cm
FAI70653	SelectWound Ag AgLI30 10x12.5cm
FAI70815	SelectWound Ag AgLI30 10x12cm
FAI70661	SelectWound Ag AgLI30 10x20cm
FAI70669	SelectWound Ag AgLI30 15x15cm
FAI70677	SelectWound Ag AgLI30 15x20cm
FAI70819	SelectWound Ag AgLI30 1x30cm
FAI70820	SelectWound Ag AgLI30 1x45cm
FAI70821	SelectWound Ag AgLI30 20x20cm
FAI70685	SelectWound Ag AgLI30 20x30cm
FAI70813	SelectWound Ag AgLI30 2x30cm
FAI70814	SelectWound Ag AgLI30 2x45cm
FAI70816	SelectWound Ag AgLI30 4x10cm
FAI70817	SelectWound Ag AgLI30 4x20cm
FAI70818	SelectWound Ag AgLI30 4x30cm
FAI70694	SelectWound Ag AgLI30 5x5cm
FAI70823	SelectWound Ag AgW330 10x10cm
FAI70824	SelectWound Ag AgW330 10x12.5cm
FAI70829	SelectWound Ag AgW330 10x12cm
FAI70825	SelectWound Ag AgW330 10x20cm
FAI70826	SelectWound Ag AgW330 15x15cm
FAI70827	SelectWound Ag AgW330 15x20cm
FAI70834	SelectWound Ag AgW330 1x30cm
FAI70835	SelectWound Ag AgW330 1x45cm
FAI70830	SelectWound Ag AgW330 20x20cm
FAI70828	SelectWound Ag AgW330 20x30cm
FAI70627	SelectWound Ag AgW330 2x30cm
FAI70635	SelectWound Ag AgW330 2x45cm
FAI70831	SelectWound Ag AgW330 4x10cm
FAI70832	SelectWound Ag AgW330 4x20cm
FAI70833	SelectWound Ag AgW330 4x30cm
FAI70822	SelectWound Ag AgW330 5x5cm

Model: Silver Alginate

Concerned medical devices;

Product Codes / References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
FAI70646	Silver Alginate AgLI30 10x10cm
FAI70662	Silver Alginate AgLI30 10x12.5cm
FAI70654	Silver Alginate AgLI30 10x12cm
FAI70670	Silver Alginate AgLI30 10x20cm
FAI70678	Silver Alginate AgLI30 15x15cm
FAI70686	Silver Alginate AgLI30 15x20cm
FAI70841	Silver Alginate AgLI30 1x30cm
FAI70842	Silver Alginate AgLI30 1x45cm
FAI70843	Silver Alginate AgLI30 20x20cm
FAI70688	Silver Alginate AgLI30 20x30cm
FAI70836	Silver Alginate AgLI30 2x30cm
FAI70837	Silver Alginate AgLI30 2x45cm
FAI70838	Silver Alginate AgLI30 4x10cm
FAI70839	Silver Alginate AgLI30 4x20cm
FAI70840	Silver Alginate AgLI30 4x30cm
FAI70695	Silver Alginate AgLI30 5x5cm
FAI70845	Silver Alginate AgW330 10x10cm
FAI70846	Silver Alginate AgW330 10x12.5cm
FAI70851	Silver Alginate AgW330 10x12cm
FA270847	Silver Alginate AgW330 10x20cm
FAI70848	Silver Alginate AgW330 15x15cm
FAI70849	Silver Alginate AgW330 15x20cm
FAI70615	Silver Alginate AgW330 1x30cm
FAI70616	Silver Alginate AgW330 1x45cm
FAI70852	Silver Alginate AgW330 20x20cm
FAI70850	Silver Alginate AgW330 20x30cm
FAI70617	Silver Alginate AgW330 2x30cm
FAI70628	Silver Alginate AgW330 2x45cm
FAI70636	Silver Alginate AgW330 4x10cm
FAI70638	Silver Alginate AgW330 4x20cm
FAI70639	Silver Alginate AgW330 4x30cm
FAI70844	Silver Alginate AgW330 5x5cm

Model: Suprasorb A+Ag

Concerned medical devices;

<u>Product Codes / References</u> <u>(codes on DofCs)</u>	<u>Product Variants</u> <u>(Commercial Name/Dimensions)</u>
20571	Suprasorb A+Ag AgLI30 10x10cm
FAI70655	Suprasorb A+Ag AgLI30 10x12.5cm
FAI70855	Suprasorb A+Ag AgLI30 10x12cm
20572	Suprasorb A+Ag AgLI30 10x20cm
FAI70671	Suprasorb A+Ag AgLI30 15x15cm
FAI70679	Suprasorb A+Ag AgLI30 15x20cm
FAI70859	Suprasorb A+Ag AgLI30 1x30cm
FAI70865	Suprasorb A+Ag AgLI30 1x45cm
FAI70866	Suprasorb A+Ag AgLI30 20x20cm
FAI70687	Suprasorb A+Ag AgLI30 20x30cm
FAI70853	Suprasorb A+Ag AgLI30 2x30cm
FAI70854	Suprasorb A+Ag AgLI30 2x45cm
FAI70856	Suprasorb A+Ag AgLI30 4x10cm
FAI70857	Suprasorb A+Ag AgLI30 4x20cm
FAI70858	Suprasorb A+Ag AgLI30 4x30cm
20570	Suprasorb A+Ag AgLI30 5x5cm
FAI70868	Suprasorb A+Ag AgW330 10x10cm
FAI70869	Suprasorb A+Ag AgW330 10x12.5cm
FAI70874	Suprasorb A+Ag AgW330 10x12cm
FAI70870	Suprasorb A+Ag AgW330 10x20cm
FAI70871	Suprasorb A+Ag AgW330 15x15cm
FAI70872	Suprasorb A+Ag AgW330 15x20cm
FAI70879	Suprasorb A+Ag AgW330 1x30cm
FAI70880	Suprasorb A+Ag AgW330 1x45cm
FAI70875	Suprasorb A+Ag AgW330 20x20cm
FAI70873	Suprasorb A+Ag AgW330 20x30cm
20573	Suprasorb A+Ag AgW330 2x30cm
FAI70637	Suprasorb A+Ag AgW330 2x45cm
FAI70876	Suprasorb A+Ag AgW330 4x10cm
FAI70877	Suprasorb A+Ag AgW330 4x20cm
FAI70878	Suprasorb A+Ag AgW330 4x30cm
FAI70867	Suprasorb A+Ag AgW330 5x5cm

MDCG 2020-3 DEĞİŞİKLİK DOĞRULAMA FORMU

MDCG 2020-3 Change Verification Form



Tarih: Date:	06.06.2024
Referans No: Reference No:	MY-23-002495 Rev. 02

Dear Sir/Madam,

Your following proposed change is reviewed according to the MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.

EC Sertifika Bilgileri Information on EC Certificate	
EC Sertifika No: EC Certificate No:	1984-MDD-21-752 1984-MDD-21-754 1984-MDD-21-769
Revizyon bilgileri: Revision:	1984-MDD-21-752 Rev. 01 (05.05.2021) 1984-MDD-21-754 Rev. 00 (16.04.2021) 1984-MDD-21-769 Rev. 00 (05.05.2021)
İmalatçı : Manufacturer:	Speciality Fibres and Materials Limited
Son Geçerlilik Tarihi: Expiry Date:	31.12.2027
Değişiklik Önerisine İlişkin Bilgiler Information on Proposed Change	
Değişiklik konusu: Subject of Change:	<p>Amendment Kiwa MY-23-002495 Appendix 1 Rev.01 :For 1984-MDD-21-769 Annex II including Section 4 (Venus Ag):</p> <p>1984-MDD-21-769 (Venus Ag) certificate includes Sequana Fiber Ag model name, the " Sequana Fiber Ag" brand(model) name was replaced with " Avarus Ag Silver Gelling Fibre" in 2021 (Kiwa MDCG 2020-3 Change Verification Form, Reference No: MY-21-002017, date: 25.11.2021). Now "Avarus Ag Silver Gelling Fibre" brand(model) name and relevant product codes (reference numbers) is going to be changed.</p> <p>A) The full list of DuraFiber Ag Pro variants is attached to this amendment as Appendix 1. For 1984-MDD-21-754 Annex II including Section 4 (Silver Alginate):</p> <p>Changing product codes for the four variants of the Suprasorb A+Ag</p> <p>B) The full list of Suprasorb A+Ag variants is attached to this amendment as Appendix 2.</p> <p>Amendment Kiwa MY-23-002495 Appendix 1 Rev. 02: For 1984-MDD-21-769 Annex II including Section 4 (Venus Ag): The product code FV000995 of the DuraFiber Ag Pro model of the Venus Ag product, trade name DuraFiber Ag Pro 160, has been corrected as 5x5 cm.</p>

The implementation of the above change proposed by Speciality Fibres and Materials Limited not represent a significant change in the design and usage purpose within the scope of MDR Article 120(3).

The above-mentioned EC certificate is valid until its expiration date and is subject to the successful completion of periodic surveillance audits.

This letter is valid when presented together with the EC Certificate mentioned above.

Sincerely,

Mustafa Serkan Sevimli
Medical Devices Division Manager

MDCG 2020-3 DEĞİŞİKLİK DOĞRULAMA FORMU
MDCG 2020-3 Change Verification Form



Amendment Kiwa MY-23-002495 Appendix 1

Product: Venus Ag

Model: DuraFiber Ag Pro

Concerned medical devices;

<u>Product Code/References (codes on DofCs)</u>	<u>Product Variants (Commercial Name/Dimensions)</u>
FV000970	DuraFiber Ag Pro 120 10x10cm
FV000973	DuraFiber Ag Pro 120 10x12.5cm
FV000974	DuraFiber Ag Pro 120 10x12cm
FV000975	DuraFiber Ag Pro 120 10x20cm
FV000976	DuraFiber Ag Pro 120 15x15cm
FV000977	DuraFiber Ag Pro 120 15x20cm
FV000978	DuraFiber Ag Pro 120 1x30cm
FV000979	DuraFiber Ag Pro 120 1x45cm
FV000980	DuraFiber Ag Pro 120 20x20cm
FV000981	DuraFiber Ag Pro 120 20x30cm
FV000982	DuraFiber Ag Pro 120 2x30cm
FV000983	DuraFiber Ag Pro 120 2x45cm
FV000984	DuraFiber Ag Pro 120 4x10cm
FV000985	DuraFiber Ag Pro 120 4x20cm
FV000986	DuraFiber Ag Pro 120 4x30cm
FV000987	DuraFiber Ag Pro 120 5x5cm
FV000971	DuraFiber Ag Pro 160 10x10cm
FV000988	DuraFiber Ag Pro 160 10x12.5cm
FV000989	DuraFiber Ag Pro 160 10x12cm
FV000990	DuraFiber Ag Pro 160 10x20cm
FV000991	DuraFiber Ag Pro 160 15x15cm
FV000992	DuraFiber Ag Pro 160 15x20cm
FV000993	DuraFiber Ag Pro 160 1x30cm
FV000994	DuraFiber Ag Pro 160 1x45cm
FV000995	DuraFiber Ag Pro 160 5x5cm
FV000996	DuraFiber Ag Pro 160 20x20cm
FV000997	DuraFiber Ag Pro 160 20x30cm
FV000998	DuraFiber Ag Pro 160 2x30cm
FV000999	DuraFiber Ag Pro 160 2x45cm
FV001000	DuraFiber Ag Pro 160 4x10cm
FV001001	DuraFiber Ag Pro 160 4x20cm



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<u>Product Code/References (codes on DofCs)</u>	<u>Product Variants (Commercial Name/Dimensions)</u>
FV001002	DuraFiber Ag Pro 160 4x30cm
FV000972	DuraFiber Ag Pro 200 10x10cm
FV001003	DuraFiber Ag Pro 200 10x12.5cm
FV001004	DuraFiber Ag Pro 200 10x12cm
FV001005	DuraFiber Ag Pro 200 10x20cm
FV001006	DuraFiber Ag Pro 200 15x15cm
FV001007	DuraFiber Ag Pro 200 15x20cm
FV001008	DuraFiber Ag Pro 200 1x30cm
FV001009	DuraFiber Ag Pro 200 1x45cm
FV001010	DuraFiber Ag Pro 200 20x20cm
FV001011	DuraFiber Ag Pro 200 20x30cm
FV001012	DuraFiber Ag Pro 200 2x30cm
FV001013	DuraFiber Ag Pro 200 2x45cm
FV001014	DuraFiber Ag Pro 200 4x10cm
FV001015	DuraFiber Ag Pro 200 4x20cm
FV001016	DuraFiber Ag Pro 200 4x30cm
FV001017	DuraFiber Ag Pro 200 5x5cm

MDCG 2020-3 DEĞİŞİKLİK DOĞRULAMA FORMU
MDCG 2020-3 Change Verification Form



Amendment Kiwa MY-23-002495 Appendix 2

Product: Silver Alginate

Model: Suprasorb A+Ag

Product Codes/References (codes on DofCs)	Product Variants (Commercial Name/Dimensions)
20571	Suprasorb A+Ag AgL130 10x10cm
FA170655	Suprasorb A+Ag AgL130 10x12.5cm
FA170855	Suprasorb A+Ag AgL130 10x12cm
20572	Suprasorb A+Ag AgL130 10x20cm
FA170671	Suprasorb A+Ag AgL130 15x15cm
FA170679	Suprasorb A+Ag AgL130 15x20cm
FA170859	Suprasorb A+Ag AgL130 1x30cm
FA170865	Suprasorb A+Ag AgL130 1x45cm
FA170866	Suprasorb A+Ag AgL130 20x20cm
FA170687	Suprasorb A+Ag AgL130 20x30cm
FA170853	Suprasorb A+Ag AgL130 2x30cm
FA170854	Suprasorb A+Ag AgL130 2x45cm
FA170856	Suprasorb A+Ag AgL130 4x10cm
FA170857	Suprasorb A+Ag AgL130 4x20cm
FA170858	Suprasorb A+Ag AgL130 4x30cm
20570	Suprasorb A+Ag AgL130 5x5cm
FA170868	Suprasorb A+Ag AgW330 10x10cm
FA170869	Suprasorb A+Ag AgW330 10x12.5cm
FA170874	Suprasorb A+Ag AgW330 10x12cm
FA170870	Suprasorb A+Ag AgW330 10x20cm
FA170871	Suprasorb A+Ag AgW330 15x15cm
FA170872	Suprasorb A+Ag AgW330 15x20cm
FA170879	Suprasorb A+Ag AgW330 1x30cm
FA170880	Suprasorb A+Ag AgW330 1x45cm
FA170875	Suprasorb A+Ag AgW330 20x20cm
FA170873	Suprasorb A+Ag AgW330 20x30cm
20573	Suprasorb A+Ag AgW330 2x30cm
FA170637	Suprasorb A+Ag AgW330 2x45cm
FA170876	Suprasorb A+Ag AgW330 4x10cm
FA170877	Suprasorb A+Ag AgW330 4x20cm
FA170878	Suprasorb A+Ag AgW330 4x30cm
FA170867	Suprasorb A+Ag AgW330 5x5cm