Manufacturer's Declaration

in relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Speciality Fibres and Materials Ltd
Manufacturer address and contact details	Galaxy House, Herald Way, Coventry, CV3 2RQ, United Kingdom
Single Registration Number (SRN) (if available)	GB-MF-000004153

Authorised Representative name (if applicable)	Advena Ltd
Authorised Representative address and contact details	Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, Malta
Single Registration Number (SRN) (if available)	MT-AR-000000234

Notified body name (if applicable)	□ See attached schedule
Notified body number (if applicable)	□ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

	□ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

☒ Expired/expires *after* 20 March 2023:

☒ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

- **Upclassified devices**

  In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

  Choose one applicable statement:

  - ☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  - ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

  - *Choose one applicable statement:*
    - ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
    - ☒ A QMS in accordance with Article 10(9) MDR is in place.
    - ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

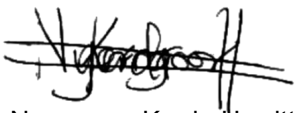
- **Device(s) as listed in the attached schedule**

  - The device(s) continue to comply with the AIMDD or MDD.
  - The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Speciality Fibres and Materials Ltd

Coventry, 04th July 2024



Nyerngoor Korda Hewitt

Director of Regulatory Affairs and Quality

Schedule of devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device (eg., device name, family/group name device model or catalogue number)	**L&R REF Number**	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)**	**Notified Body name and number**	**End date of extended validity/ transition period**	**Substitute Device** (if applicable)
Suprasorb Liquacel	33435- 33438	CE 620062	2024-05-26	BSI. 2797	2028-12-31	N/A
Suprasorb Liquacel Ag	142503 – 142506, 148145 – 148146	1984-MDD-21-769	2024-05-27	KIWA 1984	2027-12-31	N/A
Suprasorb Liquacel Pro	149710 - 149715	CE 620062	2024-05-26	BSI. 2797	2028-12-31	N/A
Suprasorb A+Ag Pro	33926 - 33929	984-MDD-21-753	2024-05-27	KIWA 1984	2027-12-31	N/A

Date: 09.07.2024

Letter of Authorisation

Venus Ag and Saturn Wound Dressings and Rope

Dear Sir/Madam,

We, Speciality Fibres and Materials Ltd located at Galaxy House 31 Herald Way, Coventry - CV3 2RQ, United Kingdom, with the European representative Advena Limited of address Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta, herewith confirm that we are the legal manufacturer of Suprasorb Liquacel Ag and Suprasorb Liquacel, and we hereby authorise the company Lohmann and Rauscher GmbH & Co. KG with offices at Irlicher Straße 55, 56567 Neuwied, Germany, to sell the following products:

Product Reference SFM		**Product Reference L&R**
Venus Ag		**Suprasorb® Liquacel Ag**
160gsm, 5x5cm	FV000246	142503
160gsm, 10x10cm	FV000247	142504
160gsm, 15x15cm	FV000249	142505
160gsm, 2x45cm	FV000250	142506
160gsm, 4x10cm	FV000263	148145
160gsm, 20x30cm	FV000264	148146
Saturn		**Suprasorb® Liquacel**
120gsm, 5x5cm	180020, 180024	180020, 180024
120gsm, 10x10cm	180021, 180026	180021, 180026
120gsm, 15x15cm	180022, 180027	180022, 180027
120gsm, 2x45cm	180023, 180028	180023, 180028

Best Regards,

09.07.2024

Nyerngoor Korda Hewitt
Director of Regulatory Affairs and Quality
Speciality Fibres and Materials Ltd.