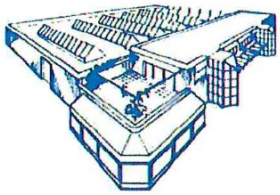
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Addendum to the EC Declaration of Conformity APPLIMED/DOCQ/11062021/V10 CED.DTE.001_31

Reason for addendum issuance: ensure completeness of the document as per Directive 93/42

Note: Article 122 of the MDR repeals Directive 93/42 as of May 26, 2021. As a result, after May 26, 2021, no more new declarations of conformity can be signed under Directive 93/42, which is why the present addendum is created in complement of the declaration of conformity.

Applimed SA declares that the following declaration of conformity was built under its sole responsibility:

APPLIMED/DOCQ/11062021/V10 CED.DTE.001_31

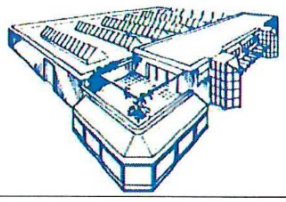
The above cited Declaration of Conformity covers the group(s) of devices mentioned in Table 1 as per EC certificate n°CH19/1051 valid from the 16th of December 2019 until the 10th of April 2023. The corresponding product list has been amended, the updated list can also be found in table 1.

Note: each product change has been tracked as per our Quality Management System (ISO 13485 certified) and assessed as non-significant as per MDCG guidance 2020-3 to ensure full compliance to Article 120 of MDR (EU) 2017/745. Applimed benefits from the extension period until the 31st of December 2028 as per extension confirmation letter from SGS with the reference CLNB1639 - HU/ BUD/20148246.

Table 1: Product group(s) and their corresponding Basic UDI-DI, Article number and product name.

Group and Basic UDI-DI	Article N°	Product/Family name
Ablation Suture Sets 0764017844SSetAbl0YX	4901047	Set : Suture
	4901067	Set : Suture
	4901064	Set : Suture
	4901082	Set : Suture
	4901108	Set : Suture
	4903232	Set : Emergency Ablation Suture
	4903236	Set : Emergency Ablation Suture
	4909773	Set : Suture
Care Sets 0764017844SSetCar0ZS	4901096	Set : Wound Care (bandage)
	4908013	Set : Bandage 10
	4908808	Set : Bandage
	4909083	Set : Wound Care (bandage)
	4909683	Set : Wound Care (disinfection)
	4909772	Set : Wound Care (disinfection)
	4909798	Set : Care
	4909804	Set : Emergency

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Group and Basic UDI-DI	Article N°	Product/Family name
Injection Sets 0764017844SSetInj04G	4909103	Set : Injection
Care Sets with syringe 0764017844SSetCar425	4909101	Set : Disinfection
IUD Sets 0764017844SSetIud04Z	4902214	Set : IUD
Surgery Sets 0764017844SSetSur08H	4909740	Set : Intervention
Urology Sets 0764017844SSetUro087	4908810	Set : Urinary catheterization
	4908814	Set : Urinary catheterization
	4908817	Set : Urology
	4909878	Set: Urinary catheterization
	4909892	Set : Urinary catheterization

Sasan Danechi, Director of Applimed,

on behalf of Applimed SA.

Place: Châtel-St-Denis

Date: 26.03.2026

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EC Declaration of Conformity

Applimed SA

ZI, route Pra de Plan, 1-CH 1618, Châtel Saint Denis,

SRN: Not yet available.

Declares that the medical devices named Single Use Sterile Sets indicated in the annexed table

- are manufactured by **Applimed SA**,
- are Sterile Medical Devices
- are Medical Devices of Class IIa rule 5 and 6
- are in compliance with requirements of Annex I of the 93/42/EEC Medical Device Directive (MDD) and standards ISO 14971, ISO 15223-1, EN 1041, EN 868-5, ISO 11607-1, ISO 116072, ISO 11135
- And subject to procedure set out in the MDD 93/42/EEC Annex II (Excluding Section 4) under the supervision of Notified Body Number 1639, SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium.

Annex II EC certificate N° CH19/1051 valid from the 16th of December 2019 until the 10th of April 2023, and remains valid subject to satisfactory surveillance audits.

ISO 13485:2016 certificate N° CH12/0135 valid from the 11th April 2021 until the 10th April 2024. Recertification audit due before 12 February 2024.

Authorised Representative: Dansu A/S

Address: Sandbakken 1-3, Ganløse, DK-3660 Stenløse, Denmark

SRN: Not yet available.

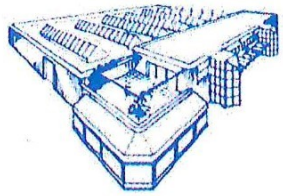
Name: MOTTER, Giancarlo

Function: Regulatory Affairs Manager (PRRC)

Place: Châtel-St-Denis

Date: 11.06.2021

APPLIMED SA

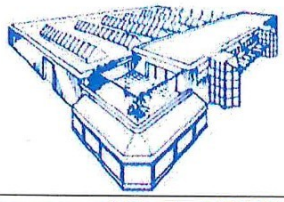


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Group and Basic UDI-DI	Article N°	Product/Family name
Ablation Suture Sets 0764017844SSetAbl0YX	4901082	Set : Suture
	4901108	Set : Suture
	4901896	Set : staple removal
	4901898	Set : fine Suture
	4903232	Set : Emergency Ablation Suture
	4903235	Set : Suture
	4903236	Set : Emergency Ablation Suture
	4908809	Set : Ablation Suture
	4909773	Set : Suture
	4909795	Set : Ablation Suture
	4909830	Set : Suture
Abscess Sets 0764017844SSetAbc0Y4	4901106	Set : Abscess
Care Sets 0764017844SSetCar0ZS	4901096	Set : Wound Care (bandage)
	4908011	Set : Bandage 5
	4908012	Set : Bandage 3
	4908013	Set : Bandage 10
	4908016	Set : Bandage 18
	4908808	Set : Bandage
	4909083	Set : Wound Care (bandage)
	4909683	Set : Wound Care (disinfection)
	4909772	Set : Wound Care (disinfection)
	4909798	Set : Care
	4909804	Set : Emergency
	4909861	Set : care
Care Sets with Pad 0764017844SSetCar323	4909744	Set : Bandage
Care Sets with syringe 0764017844SSetCar425	4909101	Set : Disinfection
Injection Sets 0764017844SSetInj04G	4909103	Set : Injection
IUD Sets 0764017844SSetIud04Z	4902214	Set : IUD
Surgery Sets 0764017844SSetSur08H	4909740	Set : Intervention

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Group and Basic UDI-DI	Article N°	Product/Family name
Urology Sets 0764017844SSetUro087	4908810	Set : Urinary catheterization
	4908814	Set : Urinary catheterization
	4908817	Set : Urology
	4909868	Set: Urinary catheterization
	4909878	Set: Urinary catheterization
	4909892	Set : Urinary catheterization
	4909925	Set : Urinary catheterization