**APPLIMED****SA**

Zone industrielle
Route de Pra de Plan 1
CH-1618 CHATEL-ST-DENIS
Switzerland

TEL : +41 (0) 21 948 92 74
FAX : +41 (0) 21 948 90 36
E-mail : info@applimed.ch
Website : www.applimed.ch

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

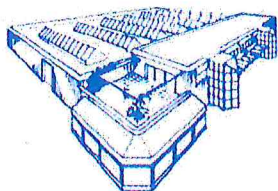
Function: Regulatory Affairs Manager (PRRC)

Place: Châtel-St-Denis

Date: 11.06.2021



APPLIMED SA



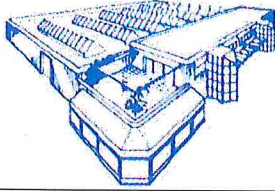
Zone industrielle
Route de Pra de Plan 1
CH-1618 CHATEL-ST-DENIS
Switzerland

TEL : +41 (0) 21 948 92 74
FAX : +41 (0) 21 948 90 36
E-mail : info@applimed.ch
Website : www.applimed.ch

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
Abscess Sets 0764017844SSetAbc0Y4	4909830	Set : Suture
	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
Care Sets with Pad 0764017844SSetCar323	4909861	Set : care
Care Sets with syringe 0764017844SSetCar425	4909744	Set : Bandage
Injection Sets 0764017844SSetInj04G	4909101	Set : Disinfection
IUD Sets 0764017844SSetIud04Z	4909103	Set : Injection
Surgery Sets 0764017844SSetSur08H	4902214	Set : IUD
	4909740	Set : Intervention



APPLIMED SA



Zone industrielle
Route de Pra de Plan 1
CH-1618 CHATEL-ST-DENIS
Switzerland

TEL : +41 (0) 21 948 92 74
FAX : +41 (0) 21 948 90 36
E-mail : info@applimed.ch
Website : www.applimed.ch

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