

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 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

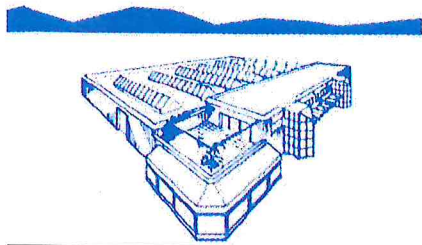
SRN: Not yet available.

Name: MOTTER, Giancarlo

Function: Regulatory Affairs Manager (PRRC)

Place: Châtel-St-Denis

Date: 11.06.2021



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Group and Basic UDI-DI	Article N°	Product/Family name
Ablation Suture Sets 0764017844SSetAbl0YX	4909750	Set : Suture
	4909961	Set : Suture
	4909962	Set : Suture
	4909963	Set : Suture
	4909968	Set : Suture
	4909969	Set : Suture
	4909971	Set : Suture
	4909993	Set: Suture
	4909996	Set : Ablation Suture
Badigeon Sets n°1 0764017844SSetBad0Y9	4909887	Set : Badigeon
Care Sets 0764017844SSetCar0ZS	4802117	Set : Care
	4909808	Set : Bandage
	4909841	Set : Bandage
	4909857	Set : Bandage
	4909859	Set : Care
	4909874	Set : shave
	4909888	Set : Big Bandage
	4909933	Set : Care
	4909946	Set : Multi-function
	4909957	Set : Care
	4909966	Set : Care
	4909994	Set : Bandage
	8001814	Set : Sterile
Care Sets with gloves 0764017844SSetCar2ZW	4802121	Set : Care
	4909867	Set: Bandage
Care Sets with syringe 0764017844SSetCar425	4909979	Set : Bandage
Childbirth Sets 0764017844SSetChi025	4909820	Set: Childbirth
Diabetology Sets 0764017844SSetDia0ZN	4909862	Set : diabetology
Gastroscopy Sets 0764017844SSetGas02U	4901094	Set: Coloscopy
Surgery Sets 0764017844SSetSur08H	4909940	Set : Rhino