

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 Is 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 V (Sterilisation only) under the supervision of Notified Body Number 1639, SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium.

Annex V EC certificate N° CH19/1050 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

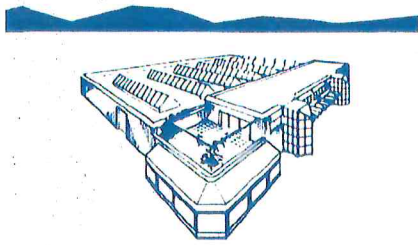
SRN: Not yet available.

Name: MOTTER, Giancarlo

Function: Regulatory Affairs Manager (PRRC)

Place: Châtel-St-Denis

Date: 11.05.2023



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Group and Basic UDI-DI	Article N°	Product/Family name
Ablation Suture Sets 0764017844SSetAbl0YX	4801120	Set : Ablation Suture
	4908014	Set : Ablation Suture (metal)
	4908020	Set : Ablation Suture (plastic)
	4909746	Set : Ablation Suture n°1
	4909747	Set : Ablation Suture n°2
	4909871	Set : Ablation Suture
Care Sets 0764017844SSetCar1ZU	4801118	Set : Wound Care (Disinfection)
	4801134	Set : Care
	4801236	Set : Care
	4901085	Set : Wound Care (Disinfection)
	4901090	Set : Wound Care (Disinfection)
	4901895	Set: Wound Care (Disinfection)
	4908010	Set : Wound care
	4908015	Set : Bandage Change n° 3
	4908018	Set : Bandage
	4908019	Set : Bandage 10
	4908021	Set : Bandage n°3
	4908022	Set : Bandage n° 18
	4908023	Set : Bandage (emergency)
	4908804	Set : cleaning
	4908805	Set : disinfection
	4909090	Set : Original
	4909394	Set : Wound Care (disinfection)
	4901045	Set : Wound Care (disinfection)
	4909675	Set : Wound Care (disinfection)
	4909677	Set : Wound Care (disinfection)
4909745	Set : Wound Care (Bandage)	
4909803	Set : Care	
Gastroscopy Sets 0764017844SSetGas02U	4909899	Set : Tracheostomy
Urology Sets 0764017844SSetUro087	4809913	Set : Urinary catheterization
	4908818	Set : Urinary Sample
	4908823	Set : Urinary catheterization
	4909906	Set : Urinary catheterization
	4909970	Set : Uricult
Vulvar Wash Sets 0764017844SSetVul08L	4809921	Set : Vulvar Wash
Wash Bladder Sets 0764017844SSetWas06C	4908811	Set : Cleaning
	4909781	Set : Wash bladder