

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 or 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

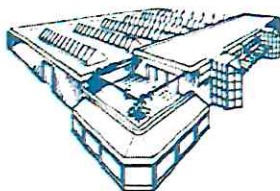
SRN: Not yet available.

Name: MOTTER, Giancarlo

Function: Regulatory Affairs Manager (PRRC)

Place: Châtel-St-Denis

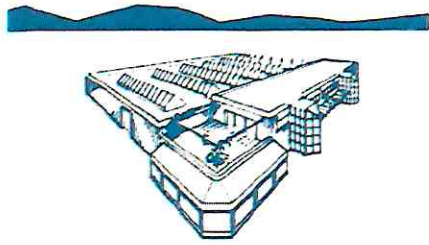
Date: 13.05.2022



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Group and Basic UDI-DI	Article N°	Product/Family name
Ablation suture Sets 0764017844SSetAbl0YX	4901083	Set : Suture
	4901089	Set : Suture B
	4903233	Set : Suture
	4909850	Set : Suture
	4909870	Set : Suture
	4909883	Set : Ablation Suture
	4909889	Set : Suture
	4909936	Set : Ablation Suture n°1
Abscess Sets 0764017844SSetAbc0Y4	4909914	Set: Abscess
	4909995	Set : Abscess
Biopsy Sets 0764017844SSetBio02M	4901006	Set: Biopsy
	4909790	Set: Biopsy Radiology
	4909792	Set : Biopsy Gynaecology
	4909793	Set: Trophoblast Supplement
	4909854	Set : Biopsy
	4909855	Set : Biopsy
	4909875	Set : Biopsy
	4909997	Set : Biopsy Radiology
Catheter Sets 0764017844SSetCat023	4901017	Set : pose Gripper
	4908820	Set : Implantable
	4908821	Set : pose venous
	4909743	Set : port-à-cath
	4909752	Set : Vascular
	4909753	Set : Thoracic
Childbirth Sets 0764017844SSetChi025	4909685	Set: Childbirth
	4909686	Set: Childbirth
	4909688	Set: Childbirth
	4909689	Set: Suture Childbirth
	4909872	Set: Umbilical
	4909821	Set : Childbirth instruments
Circumcision Sets 0764017844SSetCir035	4909757	Set : Circumcision
	4909759	Set : Circumcision
	4909760	Set : Circumcision
Infiltration Sets 0764017844SSetInf044	4803222	Set : Drainage
	4909917	Set : Infiltration
	4909919	Set : Infiltration (complet)
Ingrown Nail Sets 0764017844SSetIng047	4901097	Set : ingrown Nail
	4908827	Set: ingrown Nail
	4909844	Set : ingrown Nail
	4909849	Set : ingrown Nail
Medical Imaging Sets 0764017844SSetMed03D	4908824	Set : Radiology



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Group and Basic UDI-DI	Article N°	Product/Family name
Puncture Sets 0764017844SSetPun07G	4909102	Set : Puncture
	4909807	Set : Puncture
	4909858	Set : Puncture
	4909949	Set : Puncture
Surgery Sets 0764017844SSetSur08H	4803223	Set : intervention Surgery
	4809908	Set : ORL intervention
	4901072	Set : intervention Surgery
	4901084	Set : intervention Surgery
	4908826	Set : Surgery
	4908828	Set : Surgery
	4909093	Set : hand surgery
	4909094	Set : hand surgery
	4909643	Set : Face surgery
	4909684	Set : Episiotomy
	4909779	Set : Bandage Surgery
	4909812	Set: Surgery
	4909815	Set : small Surgery
	4909816	Set : Phlebectomy
	4909873	Set : intervention Surgery
	4909938	Set : small Surgery n°1
	4909941	Set : Intervention
4909981	Set : intervention Surgery	
4909991	Set : Surgery for dermatology	