

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 Drapes indicated in the annexed table

- are manufactured by **Applimed SA**,
- are Sterile Medical Devices
- are Medical Devices of Class Is rule 1
- 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.

Basic UDI-DI: 0764017844SDraDra0RU

Authorised Representative: Dansu A/S

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

SRN: Not yet available.

Name: MOTTER, Giancarlo

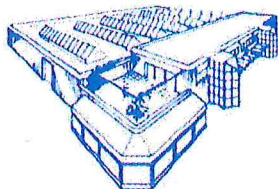
Function: Regulatory Affairs Manager (PRRC)

Place: Châtel-St-Denis

Date: 11.06.2021



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Group	Article N°	Product/Family name
Drape	4801141	Perforated Drape with adhesive, 50x60cm Hole Diameter: 8cm
	4803226	Drape, 50x50cm
	4803237	Perforated and pre-cut Drape, 60x60cm
	4803238	Perforated and pre-cut Drape, 80x80cm
	4803239	Drape, 60x60cm