

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 Tweezers 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.

Basic UDI-DI: 0764017844SInsTwe15V

Authorised Representative: Dansu A/S

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

SRN: Not yet available.

Name: MOTTER, Giancarlo

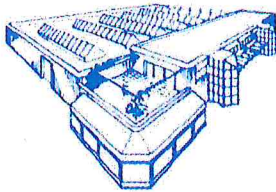
Function: Regulatory Affairs Manager (PRRC)

Place: Châtel-St-Denis

Date: 11.06.2021



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Group	Article N°	Product/Family name
Adson Tweezers	8001724	Adson Tweezers with claws, 12cm
	8001742	Adson Tweezers, 12cm, blunt
	8001745	Adson Tweezers with thin claws, 12cm
	8001755	Adson Tweezers, 12cm, blunt and thin
Feilchenfeld Tweezers	8001754	Feilchenfeld Tweezers, 9 cm
Tweezers	8001721	Anatomic Tweezers, 13cm, Thin
	8001723	Surgical Tweezers, 14cm
	8001733	Tweezers, 10.5cm
	8001921	Anatomic Tweezers, 13cm, Thin
	8001923	Surgical Tweezers, 14cm
	8001931	Anatomic Tweezers, 14cm