

**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 Tongue Depressors indicated in the annexed table

- are manufactured by **Applimed SA**,
- are Sterile Medical Devices
- are Medical Devices of Class Is rule 5
- 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 11<sup>th</sup> April 2021 until the 10<sup>th</sup> April 2024. Recertification audit due before 12 February 2024.

Basic UDI: 0764017844STonDep053

Authorised Representative: Dansu A/S

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

SRN: Not yet available.

Name: MOTTER, Giancarlo

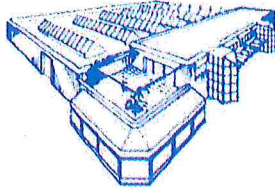
Function: Regulatory Affairs Manager (PRRC)

Place: Châtel-St-Denis

Date: 11.06.2021



# 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](mailto:info@applimed.ch)  
Website : [www.applimed.ch](http://www.applimed.ch)

| Group            | Article N° | Product/Family name           |
|------------------|------------|-------------------------------|
| Tongue Depressor | 5101802    | Tongue Depressor (wood), 15cm |
|                  | 5101803    | Tongue Depressor (wood), 15cm |