**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,

Declares that the medical devices named Single Use Scissors indicated in the annexed table

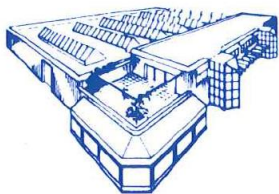
- are manufactured by **Applimed SA**,
- are Sterile Medical Devices
- are Medical Devices of Class Is rule 1
- are in compliance with requirements of Annex I of the 93/42/EEC Medical Device Directive (MDD) and standards ISO 14971, ISO 15223-1, EN 1041, EN 868-5, ISO 11607-1, ISO 11607-2, ISO 11135
- 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 2018 until the 10<sup>th</sup> April 2021. Recertification audit due before 12 February 2021.

Date: 05.05.2020

Signed by: **Mr Sasan DANECHI**



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| Group   | Article N° | Product/Family name                |
|---------|------------|------------------------------------|
| Forceps | 8001822    | Forceps for nails, 14.5cm          |
| Scissor | 8001712    | Scissor, sharp/blunt, 14cm         |
|         | 8001716    | Scissor, sharp/shap, 14cm          |
|         | 8001749    | Scissor, blunt/blunt, 14cm         |
|         | 8001813    | Lister Scissor, 14cm               |
|         | 8001816    | Scissor, blunt/blunt, 14cm, curved |
|         | 8001817    | Lister Scissor, 14cm               |
|         | 8001817    | Lister Scissor, 14cm               |
|         | 8001820    | Lister Scissor, 18cm               |
|         | 8001912    | Scissor, sharp/blunt, 14cm         |
|         | 8001916    | Scissor, sharp/sharp, 14cm         |
|         | 8001917    | Nail Scissor, 11.5 cm              |