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

# Addendum to the EC Declaration of Conformity APPLIMED/DOCQ/11062021/V8 CED.DTE.002_25

Reason for addendum issuance: ensure completeness of the document as per Directive 93/42

Note: Article 122 of the MDR repeals Directive 93/42 as of May 26, 2021. As a result, after May 26, 2021, no more new declarations of conformity can be signed under Directive 93/42, which is why the present addendum is created in complement of the declaration of conformity.

Applimed SA declares that the following declaration of conformity was built under its sole responsibility:

APPLIMED/DOCQ/11062021/V8 CED.DTE.002_25

The above cited Declaration of Conformity covers the group(s) of devices mentioned in Table 1 as per EC certificate n°CH19/1051 valid from the 16th of December 2019 until the 10th of April 2023. The corresponding product list has been amended, the updated list can also be found in table 1.

*Note: each product change has been tracked as per our Quality Management System (ISO 13485 certified) and assessed as non-significant as per MDCG guidance 2020-3 to ensure full compliance to Article 120 of MDR (EU) 2017/745. Applimed benefits from the extension period until the 31st of December 2028 as per extension confirmation letter from SGS with the reference CLNB1639 - HU/ BUD/20148246.*

Table 1: Product group(s) and their corresponding Basic UDI-DI, Article number and product name.

Basic UDI-DI: 0764017844SInsSpe04H

| Group | Article N° | Product/Family name |
|---|---|---|
| Nasal Speculum | 8001623 | Nasal Speculum (Killian), 35 mm |
| Vaginal Speculum | 4801060 | Vaginal Speculum (Cusco), 75x17mm |
| | 4801061 | Vaginal Speculum (Cusco), 80x32mm |
| | 4801062 | Vaginal Speculum (Cusco), 100x25mm |
| | 4801063 | Vaginal Speculum (Cusco), 105x27mm |

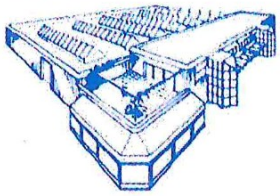
Sasan Danechi, Director of Applimed,

on behalf of Applimed SA.

APPLIMED SA
Route de Pra de Plan 1
CH-1618 Châtel-St-Denis
Phone: 021 / 948 92 74

Place: Châtel-St-Denis

Date: 13.05.2025



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 Speculums 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 11th April 2021 until the 10th April 2024. Recertification audit due before 12 February 2024.

Basic UDI-DI: 0764017844SInsSpe04H

Authorised Representative: Dansu A/S

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

SRN: Not yet available.

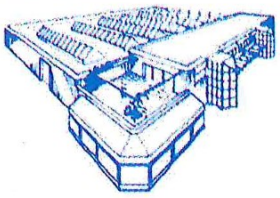
*Name: MOTTER, Giancarlo*

*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
Website : www.applimed.ch

| Group | Article N° | Product/Family name |
|---|---|---|
| Bruenings Speculum | 8001625 | Bruenings Speculum |
| Nasal Speculum | 8001623 | Nasal Speculum (killian), 35 mm |
| | 8001629 | Nasal Speculum (killian), 75 mm |
| Vaginal Speculum | 4801060 | Vaginal Speculum (Cusco), 75x17mm |
| | 4801061 | Vaginal Speculum (Cusco), 80x32mm |
| | 4801062 | Vaginal Speculum (Cusco), 100x25mm |
| | 4801063 | Vaginal Speculum (Cusco), 105x27mm |