

**Addendum to the
EC Declaration of Conformity
APPLIMED/DOCQ/11062021/V8 CED.DTE.002_43**

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_43

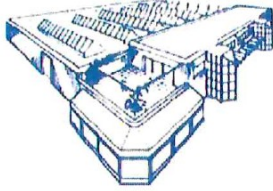
The above cited Declaration of Conformity covers the group(s) of devices mentioned in Table 1 as per EC certificate n°CH19/1051 valid from the 16th of December 2019 until the 10th of April 2023. The corresponding product list has been amended, the updated list can also be found in table 1.

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: 0764017844SInsSci12W

Group	Article N°	Product/Family name
IRIS Scissor	8001720	IRIS Scissor, 11.5cm
	8001753	IRIS Scissor, 11.5cm, curved
Jameson Scissor	8001748	Jameson Scissor, curved, 15cm, thin
Joseph Scissor	8001747	Joseph Scissor, curved, 15cm
Metzenbaum Scissor	8001757	Metzenbaum Scissor, curved, 18cm
	8001775	Metzenbaum Scissor, curved, 15cm
	8001776	Baby-Metzenbaum Scissor, curved, 11.5cm
	8001778	Metzenbaum Scissor, curved, 25cm, Thin
Schumacher Scissor	8001605	Schumacher Scissor, 16cm
Stevens Scissor	8001744	Stevens Scissor, curved, 11.5cm, thin



APPLIMED SA

Zone industrielle
Route de Pra de Plan 1
CH-1618 CHATEL-ST-DENIS
Switzerland

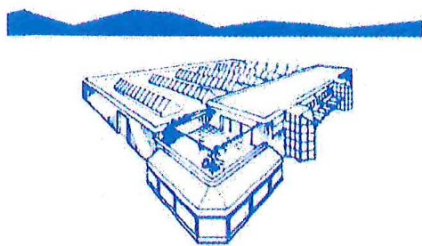
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Website : www.applimed.ch

Sasan Danechi, Director of Applimed,
on behalf of Applimed SA.

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Phone: 021 / 948 92 74

Place: Châtel-St-Denis

Date: 13.05.2025



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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 Scissors 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: 0764017844SlnsSci12W

Authorised Representative: Dansu A/S

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

SRN: Not yet available.

Name: MOTTER, Giancarlo

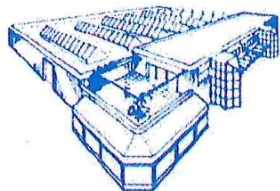
Function: Regulatory Affairs Manager (PRRC)

Place: Châtel-St-Denis

Date: 11.06.2021



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Website : www.applimed.ch

Group	Article N°	Product/Family name
IRIS Scissor	8001720	IRIS Scissor, 11.5cm
	8001753	IRIS Scissor, 11.5cm, curved
	8001811	IRIS Scissor, 11.5cm, curved and very thin
	8001920	IRIS Scissor, 11.5cm
Jameson Scissor	8001748	Jameson Scissor, curved, 15cm, thin
Joseph Scissor	8001747	Joseph Scissor, curved, 15cm
Kelly Scissor	8001618	Kelly Scissor, curved, 18cm, Thin
Metzenbaum Scissor	8001757	Metzenbaum Scissor, curved, 18cm
	8001775	Metzenbaum Scissor, curved, 15cm
	8001776	Baby-Metzenbaum Scissor, curved, 11.5cm
	8001778	Metzenbaum Scissor, curved, 25cm, Thin
Schumacher Scissor	8001605	Schumacher Scissor, 16cm
Stevens Scissor	8001744	Stevens Scissor, curved, 11.5cm, thin