EC Certificate Production Quality Assurance System: Certificate CH19/1050

The management system of

Applimed SA

Z.I. Route Pra de Plan 1
CH-1618 Châtel-Saint-Denis

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 10 April 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 10 April 2009
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered CH/GE/3301616

Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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Applimed SA

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

Issue 1

Detailed scope

Sterile single use applicators for wound care

Sterile single use compresses

Sterile single use surgical instruments set including Compress Sets

Sterile single use care set including
•Care Sets With Pad
•Mouth Care Sets

Sterile single use care set for patient preparation including
•Urology Set
•Vulvar Wash Sets
•Wash Bladder Sets
•Orthopaedic sets

Sterile single use wound care instruments including:
•Sterile curettes
•Sterile forceps
•Sterile tweezers
•Sterile speculum
•Sterile ENT Hooks and retractors

Sterile single use instruments used as accessories (Backhaus Towel Clamp, Lister Scissors, Nail Scissors, Scissors, Tweezers, Blade Holder)
Sterile single use tongue depressor
Sterile single use drape

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market

APPLIMED SA

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

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E-mail : info@applimed.ch
Website : www.applimed.ch

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Applimed SA
Manufacturer address and contact details	Z.I. Rte de Pra de Plan 1 CH – 1618 Châtel-St-Denis Switzerland Phone : +41 21 948 92 74
Single Registration Number (SRN)	Not yet available

Authorised Representative name	Dansu A/S
Authorised Representative address and contact details	Sandbakken 1-3 Ganløse 3660 Stenløse Denmark Phone: +4548181274
Single Registration Number (SRN)	Not yet available

Notified body name	SGS Belgium NV	SGS Belgium NV
Notified body number	1639	1639
Directive Certificate number(s) to which this confirmation is made	CH19/1050	CH19/1051
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	10.04.2023	10.04.2023
End date of extended validity/transition period	31.12.2028	31.12.2028

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificates** that the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificates** as listed above

- Expired *after* 20 March 2023, and
- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been submitted by us to a notified body (respecting the deadline of the 26th of May 2024) for the devices listed in the attached schedule and their substitutes and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR (respecting the deadline of the 26th of September 2024).

➢ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name:	Applimed SA
Location & Date:	Châtel-Saint-Denis, 05.07.2023
Signature, Print Name, Title:	Giancarlo MOTTER, Regulatory Affairs Manager (PRRC)
Contact Details:	giancarlo.motter@applimed.ch

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the devices	**Directive Certificate number**
Sterile single use surgical instruments including: •Sterile curettes •Sterile forceps •Sterile irrigation cannula •Sterile aspiration cannula •Sterile scissors •Sterile tweezers •Sterile retractors •Sterile hooks •Sterile probes •Sterile Forceps needle holder Sterile and Non-sterile single use surgical instruments set including: •Surgery Sets •Ablation Suture Sets •Catheter Sets •Circumcision Sets Sterile and Non-sterile single use care set including: •Care Sets with Syringe •Care Sets with Gloves •Badigeon Sets Sterile and Non-sterile single use care set for patient preparation including: •Puncture Sets •Abscess Sets •Infiltration Sets •Gastroscopy Sets •IUD Sets •Childbirth Sets •Ingrown nail Sets •Medical Imaging Sets •Injection Sets •Diabetology Sets •Biopsy Sets	CH19/1051

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Identification of the devices	**Directive Certificate number**
Sterile single use applicators for wound care Sterile single use compresses Sterile single use surgical instruments set including Compress Sets Sterile single use care set including •Care Sets With Pad •Mouth Care Sets Sterile single use care set for patient preparation including •Urology Set •Vulvar Wash Sets •Wash Bladder Sets •Orthopaedic sets Sterile single use wound care instruments including: •Sterile curettes •Sterile forceps •Sterile tweezers •Sterile speculum •Sterile ENT Hooks and retractors Sterile single use instruments used as accessories (Backhaus Towel Clamp, Lister Scissors, Nail Scissors, Scissors, Tweezers, Blade Holder) Sterile single use tongue depressor Sterile single use drape	CH19/1050