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

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Certification Manager

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Applimed SA

Directive 93/42/EEC

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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