EC Certificate Full Quality Assurance System: Certificate CH19/1051

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 II (excluding Section 4)

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 16 September 2014
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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Applimed SA

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

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**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.