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

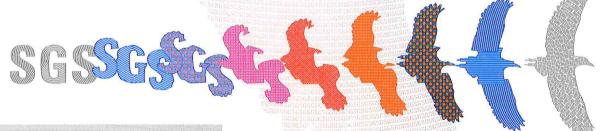
SGS Belgium NV, Notified Body 1639

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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 SetsDiabetology SetsBiopsy 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.