EC Certificate Full Quality Assurance System: Certificate CH19/1027

SGS

The management system of

Polydentia SA

Via Cantonale 47 CH-6805 Mezzovico

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

 Non-sterile tooth splinting fibers and dedicated light curing dental adhesive for conservative dentistry.

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

This certificate is valid from 16 December 2019 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 30 May 2006 and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered CH/GE 3302603

Authorised by

SGS Belgium NV, Notified Body 1639

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