

EC Certificate Full Quality Assurance System: Certificate CH10/0840

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 dental post for endodontic treatment.
- Precision drill used for the final opening of the pin/post holes in endodontic treatment.
- Tooth splinting fibers for conservative and restorative dentistry.
- Fiber Bond Light curing dental adhesive
- Rotating instruments to finish and to polish dental surfaces in restorative 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 21 June 2016 until 20 June 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 16 June 2019
Issue 6. Certified since 30 May 2006

Certification is based on reports numbered CH/GE 3302769

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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