ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 05 45735 030

Manufacturer:

3M ESPE Dental Products
2510 Conway Avenue
St. Paul MN 55144-1000
USA

EC-Representative:

3M Deutschland GmbH
Carl-Schurz-Straße 1
41453 Neuss
GERMANY

Product Category(ies):

Sterile and Non-Sterile Dental Products including: Resin Based Restorative Materials, Dental Adhesives, Primers and Cements, Pit and Fissure Sealants, Glass Ionomers, Pre-Formed Crowns, Etchants, Cavity Varnishes and Liners, Dental and Orthodontic Endosseous Implants, and Denture Relining Material

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72117260

Valid from: 2016-12-04
Valid until: 2021-12-03

Date, 2016-11-02

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Facility(ies):

3M ESPE Dental Products
2510 Conway Avenue, St. Paul MN 55144-1000, USA

3M ESPE Dental Products
2111 McGaw Avenue, Irvine CA 92614, USA

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