

3M ESPE
Dental Products

3M Center, Bldg 260-2A-11
St. Paul, MN 55144 USA



EC DECLARATION OF CONFIRMITY

Annex II, Clause 3 of Council Directive 93/42/EEC concerning Medical Devices

Manufacturer:

3M ESPE Dental Products
3M Center, Bldg 260
St. Paul, Minnesota 55144-1000
USA

EC Certificate No: G1 11 11 45735 025

Valid until: 2021-12-03

GMDN CODE: 35880

UMDNS CODE: 17-720

Manufacturing Facility:

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

Product family: BOND

Product: Single Bond Universal

EC Product Class: I
Rule: 5

CE Mark Date: Sept. 23, 2014

Per Annex IX of the Medical Device Directive

Declaration of conformity

Director - 3M ESPE

Regulatory Affairs St. Paul, Minnesota USA 2 April 2016

Signature

Title

Location

Date

3MESPE Dental Products declares that devices listed on the attached Device Schedule conform to the relevant provision of the EC Council Directive 93/42/EEC dated 14 June 1993 and are in accordance with ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes, as implemented by the European Union`s Medical Devices Regulations and verified by TuV SuD Product Service GMBH, CE 0123

EC DECLARATION OF CONFORMITY

Product family: BOND
Device Description: Single Bond Universal
EC Product Class (Per Annex IX Rules): Class: I Rule: 5

Item	Catalogue/Order number
Single Bond Universal	-