

EC DECLARATION OF CONFORMITY

CB Healthcare Consulting GmbH declares that the underneath described medical devices conform by design, manufacture and packaging to the essential requirements of the Directive 93/42/EEC concerning Medical Devices.

| REF | Description |
|---------|-----------------------|
| 9796708 | pit & fissure sealant |

UMNDS Code: 13129 Prophylaxis Kits, Dental

The products have been classified according to Annex IX, Rule 8 of the Directive as Class IIA.

Conformity with the Directive has been assessed according to Annex V. Applicable Standards are part of the Technical Documentation which can be provided on request.

This declaration of conformity is issued under the sole responsibility of the manufacturer:

CB Healthcare Consulting GmbH - Am Neumarkt 34 - 22041 Hamburg – Germany

Expiring 5 years after approval date of the EC-Certificate.

Compliance of the designated product with the Directive 93/42/EEC, as amended, has been assured via assessment of the quality management system by the Notified Body.

Notified Body: Medcert GmbH - Pilatuspool 2 - D-20355 Hamburg - Identification No.: 0482

Certification Number: 7515GB414200327

Signed for and on behalf of **CB Healthcare Consulting GmbH**:



Dr. Daniela Padula
Senior Manager Regulatory Affairs

CB Healthcare Consulting GmbH
Am Neumarkt 34
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Tuesday, March 30, 2021

Date