EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 1200911-1

Manufacturer:
Procter & Gamble Technical Centres Limited
The Heights, Brooklands
Weybridge
Surrey
KT13 0XP
United Kingdom

EUDAMED Single Registration No.: No registration number available yet

Products:

Products of class IIa:

Q0199 - Dental Devices – Others:
- Desensitisation Dentifrices

Q010280 - Devices for Prosthetic Dentistry – Accessories:
- Denture Adhesive Creams
- Denture Adhesive Powders

Products of class IIb:

D050101 - Disinfectants, Medical Devices, Peracetic Acid and Hydrogen Peroxide:
- Denture Cleansers

Authorised representative(s):
Procter & Gamble Service GmbH
Sulzbacher Str. 40
65824 Schwalbach am Taunus
Germany

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 3347348-30

Effective date: 2021-03-04

Expiry date: 2025-04-20

Issue date: 2021-03-04

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dr. T. Kießling
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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Certificate history		
Revision:	Description:	Issue date:
1	Initial certificate	2020-12-21
2	Authorised representative added	2021-03-04

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