



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Production Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

**No. G2 005390 0002 Rev. 00**

**Manufacturer:** **Dureka Dental Ltd**  
Unit 15, The Brewery Business Park  
Dundalk  
Co. Louth, A91 AV84  
IRELAND

**Product  
Category(ies):** **Dental Handpieces**

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

**Report No.:** 75942090

**Valid from:** 2019-08-21  
**Valid until:** 2024-05-26

**Date,** 2019-08-21

Stefan Preiß  
Head of Certification/Notified Body

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CERTIFICATE ♦ CERTIFICADO ♦ CERTIFIKAT ♦ 認證證書

4 / 07.17



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Unit 15, The Brewery Business Park, Dundalk, Co. Louth, A91  
AV84, IRELAND

-/-

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT