

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1264587-1

Manufacturer: Alphadent N.V.
Mannebeekstraat 33
8790 Waregem
Belgium

Products: Dental materials:
- dental attachments

Replaces Certificate, Registration No.: HD 60152405 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 3348169-30

Effective date: 2021-05-12

Expiry date: 2024-05-26

Issue date: 2021-05-12



Dipl.-Ing. U. Frenkert
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland LGA Products GmbH • 51105 Köln

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Contact

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Date February 20, 2025

Application for: QMS

Certificate No. : HD 1264587-1

Requirement : MDD Annex II excl. 4


Dear Ms. Sandrina Kreijen,

A surveillance audit of your quality management system was performed 09/2024.

The audit team confirmed that your quality management system is applied effectively with respect to the above-mentioned requirement.

Please note that the above-mentioned certificate formally expired 2024-05-26.

Best regards,

 Digital unterschrieben von
Ute Frenkert
Datum: 2025.02.20 17:56:20
+01'00'

i.V. Dipl.-Ing. U. Frenkert

Certification body

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