TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60139366 0001

Report No.: 26300358 006

Manufacturer:
OLIDENT Sp. z o.o., Sp. k.
Podleze 653
32-003 Podleze
Poland

Products:
See attachment for products included

Replaces EC Certificate. Registration No. DD 60114157 0001

Expiry Date: 2021-09-23

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-09-06

Date: 2019-09-06

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Rafal Byczkowski

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/1 Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139366 0001
Report No.: 26300358 006

Manufacturer: OLIDENT Sp. z o.o., Sp. k.
Podleze 653
32-003 Podleze
Poland

Products included:

- Dental filling/restorative materials, light cured
- Dental filling/restorative materials, light/chemically cured
- Temporary crown and bridge materials
- Dental cements
- Dental etching liquids
- Adhesives
- Composite dental posts
- Rotary dental instruments

Notified Body

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2019-09-06

Rafal Byczkowski