

EC Certificate Directive 93/42/EEC Annex V

Production Quality Assurance
Medical Devices

Registration No.: DD 60131827 0001

Report No.: 28242771 002

Manufacturer: KEROX Ipari és Kereskedelmi Kft.

Kerox utca 1 2038 Soskut Hungary

Products: ZircoStar® - Zirconia Blanks for dental applications

Expiry Date: 2023-05-07

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: 2018-09-04

Date: 2018-09-04 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.

Notified Body