

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

Registration No.: DD 60136491 0001

Report No.: 21240670 021

Manufacturer: Kulzer GmbH
Leipziger Str. 2
63450 Hanau
Deutschland

Products: - Needles, dental

Replaces Certificate, Registration No.: DD 60121463 0001

Expiry Date: 2021-02-03

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: 2019-02-01

Notified Body

Date: 2019-02-01


Dr. K. Kluge



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.