



EC-Conformity Statement

According to EC-Guideline Medical Products 93/42/EEC
Appendix V

Description of Product: Non-precious-metal dental model casting alloy on cobalt-base, type 5; Form: cylindrica; Colour: silve; Surface: smoot; Weight: ca. 6 g; Dimension: Ø 8 mm, length 15 mm

Product Name: Robur 400®

UDI-DI Primär Code: EDWA10040031

Life time: 15 years after manufacturing

Product classification: according to EC-Guideline 93/42/EEC, Appendix IX, point 2.1, the classification "class IIa", rule number 5, 3rd bullet point

The product is developed, designed and manufactured in accordance with the EC-guideline 93/42/EEC, on the only responsibility of

Eisenbacher Dentalwaren ED GmbH, Dr.-Konrad-Wiegand-Straße 9
63939 Würth am Main, Deutschland

Notified body: TÜV SÜD Product Service GmbH, Ridlerstr. 65,
80339 München



The following standards and specifications have been applied:

Specification: DIN EN ISO 22674:2016

Certifications: DIN EN ISO 13485:2016
according to Annex V of the MDD 93/42/EEC

A technical documentation and risk management are completely available.

Würth, den 29.03.2021

Signature: 
General Manager Eisenbacher Dentalwaren ED GmbH
Jennifer Maag

This declaration of conformity is valid until 26.05.2024.

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