

RECOGNITION

The Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) has determined in a recognition procedure that

BIOSERV Analytik und Medizinprodukte GmbH
Dr.-Lorenz-Weg 1
18059 Rostock
Germany

is competent under the terms of

Council Directives 93/42/EEC, 90/385/EEC and EN ISO/IEC 17025

for

biological, chemical, and microbiological-hygienic testing of medical devices and physical testing of medical devices as well as sterile barrier systems and packaging systems; environmental monitoring.

This recognition according to § 15 (5) Medical Devices Act is valid up to **2025-12-02**.

This document is valid only in conjunction with the recognition notice which contains the binding information on the recognition. The scope of the recognition is specified in the annex in force of the recognition notice and can be found on www.zlg.de.

Registration number **ZLG-AP-317.10.20**

Bonn, 2021-01-05

Dr Rainer Edelhäuser
Director of ZLG



Baden-Württemberg



Bayern



Berlin



Brandenburg



Bremen



Hamburg



Hessen



Mecklenburg-Vorpommern



Thüringen



Schleswig-Holstein



Sachsen



Sachsen-Anhalt



Saarland



Rheinland-Pfalz



Nordrhein-Westfalen



Niedersachsen

Basis of recognition

Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices

German Act on Medical Devices (Medical Devices Act)

Rules for recognition of ZLG (www.zlg.de)

- General Rules for Recognition and Designation (200 RE01)
- Rules for the Recognition of Laboratories (210 RE01)

EN ISO/IEC 17025 : 2017-12 General requirements for the competence of testing and calibration laboratories

For the use of indications on the status of recognition the document of ZLG 200 HI02 applies (www.zlg.de).