Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

Baden-Württemberg

Bayern

Berlin

Brandenburg

Bremen

Hamburg

Hessen

Mecklenburg-Vorpommern

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

Questmed GmbH

Albert-Einstein-Ring 9
14532 Kleinmachnow
Germany

is competent under the term of

the Council Directive 93/42/EEC and EN ISO/IEC 17025

for

physical and physical-chemical testing of non-active implants

This recognition according to § 15 (5) Medical Devices Act is valid up to **2023-05-28**.

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-225.10.75**

Bonn, 2020-03-04

Dr Ulrich Poos
Deputy of Director of ZLG

Thüringen

Schleswig-Holstein

Sachsen

Sachsen-Anhalt

Saarland

Rheinland-Pfalz

Nordrhein-Westfalen

Niedersachsen

Basis of recognition

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 : 2018-03	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).