EU Certificate

for the assessment of the quality management system

according to Medical Device Regulation (EU) 2017/745 Annex IX Chapter I+III

As a Notified Body of the European Union DEKRA Certification GmbH certifies, that the manufacturer

Raimund Wenzler GmbH Instrumenten-Manufaktur

Single Registration Number (SRN): DE-MF-000018322
Steigäcker 22, 78582 Balgheim, Germany

applies a quality management system according to Annex IX Chapter I+III of the Medical Device Regulation (EU) 2017/745 for the medical devices listed in the annex. This certificate is based on the assessments listed in CNo51483-00, Rev. 1 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 51483-60-00-01

Certificate valid from: 2026-08-28
Certificate valid to: 2031-03-02

Previous certificate no. 51483-60-00-00, issued on 2026-03-03

Digital unterschrieben von
Stephanie Donner
Datum: 2026-08-28 14:55:19+02:00

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-092

DEKRA Certification GmbH, Stuttgart
Notified Body ID number: 0124

Annex to the EU Certificate no. 51483-60-00-01

Following devices/device categories are included in this certificate:

Class Ir

For the devices listed below, the review of the quality management system refers exclusively to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

MDN 1208

- Rongeurs for neurosurgery and laminectomy:

  Basic UDI-DI: 42555734RONGEURE_NEURO8D

Change(s) to previous certificate: validity of certificate extended