

QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-492-135-1809

The **Directorate of Device Testing and Clinical Engineering (EMKI)**
as a Certification Body with ID No. NAH-4-0096/2016
accredited by the National Accreditation Authority for management system certification
certifies that the quality management system applied by

BIOTECH GmbH
Hagenauer Str. 17-19, 65203 Wiesbaden
Germany
and
Magyarországi Fióktelepe
Petőfi Sándor utca 43-47, 2049 Diósd
Hungary

meets the requirements of standard

EN ISO 13485:2016

in the field:

**Design, development, manufacture and distribution
of non active surgical implant systems;
Design, development, manufacture and distribution
of surgical instrument systems**

Registry number of the related audit report: **43-066-2007**

This certificate is valid until **2021-09-08** supposed that the results of the regular yearly
surveillance audits are satisfactory.

Budapest, 2018-09-09



Head of EMKI



EMKI 2092

The authenticity and validity of the certificate are verifiable at EMKI.

Eszközminősítő és Kórháztechnikai Igazgatóság
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