

QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 4-418-135-1509

National Institute of Pharmacy and Nutrition

Directorate of Device Testing and Clinical Engineering (EMKI)

as a Certification Body with ID No. NAT-4-0096/2012
accredited by the Hungarian Accreditation Board for management system certification
certifies that the quality management system applied by

BIOTECH GmbH

**Unter den Eichen 5., Gebäude F, 3. OG, 65195 Wiesbaden
Germany**

**Magyarországi Fióktelepe
Petőfi Sándor utca 43-47., 2049 Diósd
Hungary**

meets the requirements of standard

EN ISO 13485:2012

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 **2018-09-08** supposed that the results of the regular yearly surveillance audits are satisfactory.

Budapest, 2015-09-09



Deputy General Director

Head of EMKI



EMKI 1347

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

Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet
National Institute of Pharmacy and Nutrition
Eszközminősítő és Kórháztechnikai Igazgatóság
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