

QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 1-357-901-1509

National Institute of Pharmacy and Nutrition

Directorate of Device Testing and Clinical Engineering (EMKI)

as a Certification Body with ID No. NAT-4-0009/2012
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 9001:2008

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 1345

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
Directorate of Device Testing and Clinical Engineering

H-1051 Budapest, Zrínyi u. 3., Telefon: +36 1 886 93 00, Fax: +36 1 886 94 60
H-1125 Budapest, Diós árok 3., Telefon: +36 1 225 27 39, E-mail: cert@emki.hu

