

EMKI

EMKI

EMKI

EMKI

EMKI

EMKI

EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-776-200-1509

The Directorate of Device Testing and Clinical Engineering (EMKI)
certifies that the manufacturer:

Biotech GmbH
Hagenauer Str. 17-19
65203 Wiesbaden
Germany

for the products / product category:

Sterile and non-sterile orthopaedic implant systems

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **42-066-2007**

This certificate is valid together with EC Design-Examination Certificates according to Directive 93/42/EEC on Medical Devices, Annex II (4) No. **5-777-204-1509** and No. **5-778-204-1509**.

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

Issued by EMKI as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 5

First issued: 2015-09-09

Budapest, 2018-05-16

Head of EMKI



EMKI 2007

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

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33

E-mail: cert@emki.hu, Web: www.emki.hu

H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)

EMKI

ATTACHMENT TO EC CERTIFICATE

Page 1 of 1

Additional information for Certificate No. 5-776-200-1509

The certificate is valid for the following manufacturing sites / facilities:

Biotech GmbH
Hagenauer Str. 17-19
65203 Wiesbaden, Germany

Biotech GmbH Magyarországi Fióktelepe
Petőfi Sándor utca 43-47
2049 Diósd, Hungary

The certificate is valid for the following products:

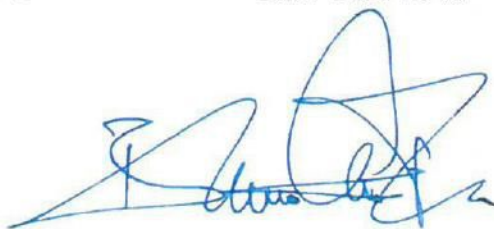
<i>Sterile and non-sterile orthopaedic implant systems</i>	<i>Class</i>
Biotech Sterile Knee Endoprosthesis Systems	III
Instruments and Trial Tray for Biotech Sterile Knee Endoprosthesis Systems	IIa
Biotech Sterile Hip Endoprosthesis Systems	III
Instruments and Trial Tray for Biotech Sterile Hip Endoprosthesis Systems	IIa
Biotech Traumatological Implant Systems for Osteosynthesis	IIb
Biotech Pectus Bar Correct System	IIb
Biotech Spinal Implant System	IIb

The detailed product list is kept by EMKI under No. 42-066-2007.

Issue: 5

Date: 2018-05-16

First issued: 2015-09-09



Head of EMKI



EMKI

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33

E-mail: cert@emki.hu, Web: www.emki.hu

H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)

