EC CERTIFICATE

Full Quality Assurance System

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

No. 5-903-200-2103

The **NEOEMKI National Medical Device Conformity Assessment and Certification LLC.** 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: **NE/1010/2021**

This certificate is valid together with EC Design-Examination Certificates according to Directive 93/42/EEC on Medical Devices, Annex II (4) **No. 5-904-204-2103** and **No. 5-905-204-2103**.

This certificate is valid until **2024-05-26** supposed that the results of the regular yearly surveillance audits are satisfactory.

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

This certificate is valid only with the attachment.

Budapest, 2021-03-09

László Imre
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

EMKI 2680

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

ATTACHMENT TO EC CERTIFICATE

Additional information for Certificate No. 5-903-200-2103

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:

Sterile and non-sterile orthopaedic implant systems	***Class***
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 NEOEMKI LLC. under No. 1010/2020.

Issue: 1 Date: 2021-03-09 First issued: 2021-03-09

László Imre
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

EMKI

EC DESIGN-EXAMINATION CERTIFICATE

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

No. 5-904-204-2103

The **NEOEMKI National Medical Device Conformity Assessment and Certification LLC.** certifies that the following manufacturer's

Biotech GmbH
Hagenauer Str. 17-19
65203 Wiesbaden
Germany

product's

Biotech Sterile Knee Endoprosthesis System

(models listed in the attachment)

design dossier conforms to the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the report on the examination of the design dossier: **NE/1010/2021**

This certificate is valid only together with EC Certificate according to Directive 93/42/EEC on Medical Devices, Annex II excluding (4) **No. 5-903-200-2103**.

This certificate is valid until: **2024-05-26**

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

This certificate is valid only with the attachment.

Budapest, 2021-03-09

László Imre
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

EMKI 2682

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

ATTACHMENT TO EC DESIGN-EXAMINATION CERTIFICATE

Additional information for Certificate No. 5-904-204-2103

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 / models:

Biotech Sterile Knee Endoprosthesis System	***Class***
TP Total Knee System	III
TRK Total Revision Knee System	III
Future Knee Modular System	III
Future Knee 1 System	III
HF - High Flexion Knee System	III
Biotech Constrained Knee System	III
BMI Unicondylar Knee System	III
TMB Total Rotating Knee System	III

The detailed product list is kept by NEOEMKI LLC. under No. 1010/2020.

Issue: 1 Date: 2021-03-09 First issued: 2021-03-09

László Imre
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

EMKI

EC DESIGN-EXAMINATION CERTIFICATE

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

No. 5-905-204-2103

The **NEOEMKI National Medical Device Conformity Assessment and Certification LLC.** certifies that the following manufacturer's

Biotech GmbH
Hagenauer Str. 17-19
65203 Wiesbaden
Germany

product's

Biotech Sterile Hip Endoprosthesis System

(models listed in the attachment)

design dossier conforms to the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the report on the examination of the design dossier: **NE/1010/2021**

This certificate is valid only together with EC Certificate according to Directive 93/42/EEC on Medical Devices, Annex II excluding (4) **No. 5-903-200-2103**.

This certificate is valid until: **2024-05-26**

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

This certificate is valid only with the attachment.

Budapest, 2021-03-09

László Imre
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

EMKI 2684

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

ATTACHMENT TO EC DESIGN-EXAMINATION CERTIFICATE

Additional information for Certificate No. 5-905-204-2103

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 / models:

Biotech Sterile Hip Endoprosthesis System	***Class***
Biotech Modular Head System	III
Biotech Acetabular Cup System	III
BA Hip Stem System	III
SKM Hip Stem System	III
BET Hip Stem System	III
BQS Hip Stem System	III
Biotech Modular Revision Hip Stem System	III
Austin Moore Hip Stem System	III

The detailed product list is kept by NEOEMKI LLC. under No. 1010/2020.

Issue: 1 Date: 2021-03-09 First issued: 2021-03-09

László Imre
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

EMKI

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 **2022-09-08** supposed that the results of the regular yearly surveillance audits are satisfactory.

Budapest, 2019-09-09

Head of EMKI

EMKI 2092

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.)