

## EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

### Full Quality Assurance System

Certificate Number: 2195-MED-1820101

**Manufacturer:** BIOTRH s.r.o.  
Lyčkovo náměstí 508/7, Karlín, 186 00 Prague 8, CZECH REPUBLIC

**Product(s):** Sterile Hydrophilic Gel for Endoprothetics of Human Soft Tissues

**Model(s):** Los Deline 25g, Los Deline 100g

**Reference Report No:** MM0654-P004-R01, MM0654-P004-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

*This EC certificate is valid till 2024-05-26.*

Issue Date: 2018-07-20  
Revision No.: 01 Recertification  
Revision Date: 2020-02-19



Rukiye BALKAN  
Deputy General Manager

## EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

**Certificate Number: 2195-MED-1820101-D01**

**Manufacturer:** BIOTRH s.r.o.  
Lyčkovo náměstí 508/7, Karlín, 186 00 Prague 8, CZECH REPUBLIC

**Product(s):** Sterile Hydrophilic Gel for Endoprothetics of Human Soft Tissues

**Model(s):** Los Deline 25g, Los Deline 100g

**Reference Report No:** MM0654-P004-R01, MM0654-P004-R02

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.

The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

*This EC Design Examination certificate is valid till 2024-05-26.*

Issue Date: 2018-07-20  
Revision No.: 01 Recertification  
Revision Date: 2020-02-19



Rukiye BALKAN  
Deputy General Manager