SZUTEST®

EC CERTIFICATE

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

Full Quality Assurance System

Certificate Number: 2195-MED-1418802

Manufacturer: **BioPlus Co., Ltd.**
#211, Migun Techno World 2, 187 Techno 2-ro, Yuseong-gu, Daejeon 34025, Korea

Product(s): **Sterile Absorbable Hyaluronic Acid Dermal Filler**

Model(s): **SkinPlus-HYAL** (*SkinPlus-HYAL 60, SkinPlus-HYAL 65, SkinPlus-HYAL 70, SkinPlus-HYAL 100*)

Reference Report No: **2195-MED-1407002**

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II, Section 3 and Section 4 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe and sterile 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).

This EC certificate is valid till 2019-07-06.

Issue Date: 2014-07-07
Revision No.: 01
Revision Date: 2016-03-18

Mehmet IŞIKLAR
General Manager

This version of certificate has come into force on 2013.11.06. 1/1 2195-MED-1418802 Rev.01

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SZUTEST®

EC DESIGN EXAMINATION CERTIFICATE

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

Certificate Number: 2195-MED-1418802-D01

Manufacturer: **BioPlus Co., Ltd.**
#211, Migun Techno World 2, 187 Techno 2-ro, Yuseong-gu, Daejeon 34025, Korea

Product(s): **Sterile Absorbable Hyaluronic Acid Dermal Filler**

Model(s): **SkinPlus-HYAL** (*SkinPlus-HYAL 60, SkinPlus-HYAL 65, SkinPlus-HYAL 70, SkinPlus-HYAL 100*)

Reference Report No: **2195-MED-1407002**

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 2019-07-06.

Issue Date: 2014-07-07
Revision No.: 01
Revision Date: 2016-03-18

Mehmet IŞIKLAR
General Manager

This version of certificate has come into force on 2013.11.06 . 1/1 2195-MED-1418802-D01 Rev.01

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