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.**
Plant 1: #211, Migun Techno World 2, 187 Techno 2-ro, Yuseong-gu, Daejeon, Republic of KOREA
Plant 2: A-#901, #902, #903, #904, #905, #906, #907, #1201, #1202, #1205, 14, Sagimakgol-ro, 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of KOREA

Product(s): **1. Sterile Absorbable Hyaluronic Acid Dermal Filler**
2. Sterile Absorbable Anti-Adhesion Barrier

Model(s): Product specifications are stated on the following page(s).

Reference Report No: MM0089-P006-R01, MM0089-P006-R02, MM0089-P009-R01, MM0089-P009-R02, MM0089-P011-R01, MM0089-P011-R02, MM0089-P011-R03, MM0089-P012-R01, MM0089-P012-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 2024-03-24.

Issue Date: 2014-07-07
Revision No.: 07 Rev.
Revision Date: 2020-08-31

Rukiye BALKAN
Deputy General Manager

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

Certificate Number: 2195-MED-1418802

Product Specifications:

Product Name	Model Name
1. Sterile Absorbable Hyaluronic Acid Dermal Filler	SkinPlus-HYAL 60, SkinPlus-HYAL 65, SkinPlus-HYAL 70, SkinPlus-HYAL 100, SkinPlus-HYAL 100JC, SkinPlus-HYAL 100BC, HYALDEW 200, HYALDEW-JC, HYALDEW-BC, DENEB 300, DENEB-JC, DENEB-BC, BPLN-100, BPLN-100JC, BPLN-100BC, BPLN2-100, BPLN2-100JC, BPLN2-100BC, BPL100-100C, BPL100-100BC, BPLN-60, BPLN-60JC, BPLN-60BC, BPL-60JC, BPL-60BC, BPL20-60, BPL20-60JC, BPL20-60BC, BPL30-60, BPL30-60JC, BPL30-60BC, BPL100-60C, BPL100-60BC, BPLN-27, BPLN-27JC, BPLN-27BC, BPLN-30, BPLN-30JC, BPLN-30BC, BPL-27JC, BPL-27BC, BPL20-27, BPL20-27JC, BPL20-27BC, BPL30-27, BPL30-27JC, BPL30-27BC, BPL100-27C, BPL100-27BC, BPW-30JC, BPW-30BC, BPBN-31, BPBN-31JC, BPBN-31BC, BPB27-31, BPB27-31JC, BPB27-31BC, BPL100-31C, BPL100-31BC, BPLN2-60JC, BPLN2-60BC, BPLN4-60JC, BPLN4-60BC, BPLN3-27JC, BPLN3-27BC
2. Sterile Absorbable Anti-Adhesion Barrier	BPAA-15, BPAA-30, BPAA-50, BPAA-15BC, BPAA-30BC, BPAA-50BC

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.**
Plant 1: #211, Migun Techno World 2, 187 Techno 2-ro, Yuseong-gu, Daejeon, Republic of KOREA
Plant 2: A-#901, #902, #903, #904, #905, #906, #907, #1201, #1202, #1205, 14, Sagimakgol-ro, 45beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of KOREA

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

Model(s): SkinPlus-HYAL 60, SkinPlus-HYAL 65, SkinPlus-HYAL 70, SkinPlus-HYAL 100, SkinPlus-HYAL 100JC, SkinPlus-HYAL 100BC, HYALDEW 200, HYALDEW-JC, HYALDEW-BC, DENEB 300, DENEB-JC, DENEB-BC, BPLN-100, BPLN-100JC, BPLN-100BC, BPLN2-100, BPLN2-100JC, BPLN2-100BC, BPL100-100C, BPL100-100BC, BPLN-60, BPLN-60JC, BPLN-60BC, BPL-60JC, BPL-60BC, BPL20-60, BPL20-60JC, BPL20-60BC, BPL30-60, BPL30-60JC, BPL30-60BC, BPL100-60C, BPL100-60BC, BPLN-27, BPLN-27JC, BPLN-27BC, BPLN-30, BPLN-30JC, BPLN-30BC, BPL-27JC, BPL-27BC, BPL20-27, BPL20-27JC, BPL20-27BC, BPL30-27, BPL30-27JC, BPL30-27BC, BPL100-27C, BPL100-27BC, BPW-30JC, BPW-30BC, BPBN-31, BPBN-31JC, BPBN-31BC, BPB27-31, BPB27-31JC, BPB27-31BC, BPL100-31C, BPL100-31BC, BPLN2-60JC, BPLN2-60BC, BPLN4-60JC, BPLN4-60BC, BPLN3-27JC, BPLN3-27BC

Reference Report No: MM0089-P009-R01, MM0089-P009-R02, MM0089-P011-R01, MM0089-P011-R02, MM0089-P012-R01, MM0089-P012-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 2024-03-24.

Issue Date: 2014-07-07
Revision No.: 06 Rev.
Revision Date: 2020-08-31

Rukiye BALKAN
Deputy General Manager

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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-D02

Manufacturer:	**BioPlus Co., Ltd.** #211, Migun Techno World 2, 187 Techno 2-ro, Yuseong-gu, Daejeon, Republic of KOREA
Product(s):	**Sterile Absorbable Anti-Adhesion Barrier**
Model(s):	BPAA-15, BPAA-30, BPAA-50, BPAA-15BC, BPAA-30BC, BPAA-50BC
Reference Report No:	MM0089-P006-R01, MM0089-P006-R02, MM0089-P009-R01, MM0089-P009-R02, MM0089-P011-R01, MM0089-P011-R03

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 2024-03-24.

Issue Date:	2019-01-23
Revision No.:	02 Rev.
Revision Date:	2020-08-31

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