



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2021-MDD/QS-057

issued in compliance with the Council Directive 93/42/EEC as amended,
certifies that the medical device of Class III,

Cross-Linked Hyaluronic Acid Filler

Brand names: Revitrane

(for detailed list refer to Annex)

manufactured by company

BR PHARM Co., Ltd

**13, Sinpyeong-ro, Jijeong-myeon, Wonju-si, Gangwon-do, 26348,
Republic of Korea**

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 01-094-21 and the Final protocol No. 310553/2021.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2024 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment of relevant legal and other requirements by manufacturer. For the placing on the market of the above referenced models of medical devices covered by this certificate, an EC design-examination certificate according to the Directive 93/42/EEC as amended, Annex II (4) is required.



Dr. Katarína Tomin Srdošová
Responsible to act on behalf of NB 2265

At Bratislava, on May 24th, 2021



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC DESIGN-EXAMINATION CERTIFICATE

No. 2021-MDD/DE-058

issued in compliance with the Council Directive 93/42/EEC as amended,
certifies that the design of medical device of Class III,

Cross-Linked Hyaluronic Acid Filler

Brand names: Revitrane

(for detailed list refer to Annex)

manufactured by company

BR PHARM Co., Ltd

13, Sinpyeong-ro, Jijeong-myeon, Wonju-si, Gangwon-do, 26348,
Republic of Korea

conforms with the relevant provisions of Annex II.4 of the Directive 93/42/EEC as amended on medical devices as transposed into national legislation. The device fulfils the essential requirements specified in Annex I of the Directive 93/42/EEC as amended taking into account intended purpose of the device.

The Notified Body No. 2265 has performed a design-examination of the device according to Annex II.4 of the Directive 93/42/EEC as amended. The detailed device description, design dossier and evaluation of the examination are presented in the Final protocol No. 310553/2021.

This certificate is issued under the following conditions:

It applies only to the design of the above referenced model of the medical device and it does not imply the Notified Body executed any surveillance or control of its manufacture. The manufacturer is obligated to assure that all medical devices of the respective model conform to the type whose design has been approved by this certificate. The certificate remains valid until the approved design is changed but till May 26th, 2024 at the latest. This EC design-examination certificate is complementary to an EC Certificate, approving the manufacturer's quality system according to the Directive 93/42/EEC as amended, Annex II (excluding 4).



Dr. Katarina Tomin Srdošová
Responsible to act on behalf of NB 2265

At Bratislava, on May 24th, 2021



ANNEX TO EC CERTIFICATE No. 2021-MDD/QS-057

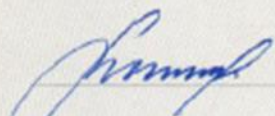
issued for the company

BR PHARM Co., Ltd
#13, Sinpyeong-ro, Jijeong-myeon, Wonju-si, Gangwon-do, 26348,
Republic of Korea


List of medical devices covered by the EC Certificate:

Brand Name	No.	Model Name	Contents	Syringe	Needle
Revitrane	1	Revitrane HA20 Skinbooster	2 ml	3 ml x 3 ea	-
	2	Revitrane HA10 Classic	1 ml	1 ml x 1 ea	30 G x 2 ea
	3	Revitrane HA10 Volume	1 ml	1 ml x 1 ea	27 G x 2 ea
	4	Revitrane HA10 Premium	1 ml	1 ml x 1 ea	27 G x 2 ea
	5	Revitrane Premium-Q	1 ml	1 ml x 1 ea	-
	6	Revitrane Sub-Q	2 ml	3 ml x 1 ea	-
	7	Revitrane Premium Sub-Q 1 ml	1 ml	1 ml x 1 ea	-
	8	Revitrane Premium Sub-Q 2 ml	2 ml	3 ml x 1 ea	-

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Dr. Katarina Tomin Srošová
Responsible to act on behalf of NB 2265



At Bratislava, on May 24th, 2021
Valid until May 26th, 2024