CERTIFICATE

notice

EC CERTIFICATE

According to Annex II (excluding article 4) of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number

CE-MDD-0095/02/2021/01

Manufacturer	:	Shanghai Reyoungel Medical Technology Company Limited
Address	:	Floor 15, Building 2#, No.1809, Qixin Road, Minhang District, 201100, Shanghai, China
Product(s)	:	Medical Cross-linked Sodium Hyaluronate Gel – Soft Tissue Filler
Report Number	:	CE-MDD-0095/02/2021/01
First Issue Date and Place	:	2021.02.26 & Istanbul
Revision Number and Date	:	00 / --
Validity Date	:	2024.05.26

NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II, 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. NOTICE must be informed of any significant changes in the design and/or construction of the product(s). This certificate is valid together with Design Certificate issued according to 93/42/EEC Annex II (Section 4) for products defined below.

Özlem Vicdan Akdağ
Chairman

NOTICE BELGELENDİRME MUAYENE VE DENETİM HİZ. A.Ş. • NB 2764

NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş.

Esentepe Mahallesi Milangaz Caddesi
No:75/A/92 Kartal / İstanbul / TÜRKİYE
www.notice.com.tr

CERTIFICATE

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Product Name	Model Name	Specifications
Medical Cross-linked Sodium Hyaluronate Gel - Soft Tissue Filler	Sub Skin	1250µm ~ 2000µm
	Derm Plus	500µm ~ 1250µm
	Derm Deep	280µm ~ 500µm
	Derm	150µm ~ 280µm
	Fine Lines	100µm ~ 150µm

NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZ A.Ş. NB 2764

NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş.

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CERTIFICATE

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EC DESIGN EXAMINATION CERTIFICATE

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

Certificate Number

CE-MDD-0095/02/2021/01/DD.01

Manufacturer	:	Shanghai Reyoungel Medical Technology Company Limited
Address	:	Floor 15, Building 2#, No.1809, Qixin Road, Minhang District, 201100, Shanghai, China
Product(s)	:	Medical Cross-linked Sodium Hyaluronate Gel - Soft Tissue Filler
Report Number	:	[illegible]
First Issue Date and Place	:	2021.02.26 & Istanbul
Revision Number and Date	:	00 / --
Validity Date	:	2024.05.26

Issued by NOTICE, Notified Body 2764, this document approves 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.

BELGELENDİRME MUAYENE VE DENETİM HİZ. A.Ş. • NOTICE • NB 2764

Özlem Vicdan Akdağ
Chairman

NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş.

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CERTIFICATE

notice

Product Name	Model Name	Specifications
Medical Cross-linked Sodium Hyaluronate Gel - Soft Tissue Filler	Sub Skin	1250μm ~ 2000μm
	Derm Plus	500μm ~ 1250μm
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NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZ A.Ş. NB 2764

NOTİCE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş.

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