3EC International SKTC-118 3EC International SKTC-118 3EC International SKTC-118

3EC®
international

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

EC DESIGN-EXAMINATION CERTIFICATE

No. 2020-MDD/DE-025

issued in compliance with the Council Directive 93/42/EEC as amended 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll., certifies that the design of medical device of Class III,

Hyaluronan Soft Tissue Filling Gel
Trade Name Manorui® Cross Linked /Non Cross Linked Hyaluronic Acid

manufactured by company

Jining Hangxing E-Commerce Co., Ltd.
No. Commercial Street Complex, Guiyuan Area, Fuqiao District, Rencheng Dist., Jining, Shandong, China

conforms with the relevant provisions of Annex II.4 of the Directive 93/42/EEC on medical devices as transposed into national legislation. The device fulfils the essential requirements specified in Annex I of the Directive 93/42/EEC taking into account intended use 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. The detailed device description, design dossier and evaluation of the examination are presented in the Final protocol No.310296A/2020.

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 November 6th, 2025 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 by 2007/47/EC, Annex II excluding (4).

Notified body
3EC International
NB 2265
NOTIFIKOVANÁ OSOBA

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

In Bratislava, on November 7th, 2020

©Tlačiareň cenín KASICO, a. s. Bratislava, 110-343-14