

144985-20-05-19

EC DESIGN-EXAMINATION CERTIFICATE

Directive 93/42/EEC on Medical devices, Annex II (4)

CE Certiso Ltd. (NB 2409) certifies that the design of the device concerning to the listed devices and device categories conforms to the requirements of the directive.

Name of the manufacturer:

BioScience GmbH

Headquarters:

Walsmühler Straße 18, D-19073 Dümmer, Germany

Scope:

Cross-linked hyaluronic acid gel dermal filler

The certificate covers the following devices:

Description of the device	Туре	Intended use	Model	Risk class
Cross-linked hyaluronic acid gel	Hylan Gel Dermal	soft tissue augmentation	CRM Gel 1 ml Genefill Soft Fill 1ml Genefill Soft Touch 1 ml Hyacorp Lips 1 ml Hyacorp Feel 2*2ml Hyacorp Face 1 ml; 2*2 ml	III

This certificate is valid only with the system certificate No. **144983-20-05-19**, in case of successfully conducted annual surveillance audits.

ID number of the related design examination report: 118-G2-190327

Issue: 1

Issued: 19 May 2020

First issued: 19 May 2020

Start date of certified status: 13 January 2016

Expires:

25 May 2024





General Manager

CE Certiso Ltd. H-2092 Budakeszi, Erdő u. 101.

Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu

NB ID number: 2409