144980-20-04-27

EC CERTIFICATE

Full Quality Assurance System

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

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

BioPolymer GmbH & Co. KG

Headquarters: **Walsmühler Straße 18, D-19073 Dümmer, Germany**

Scope:

Visco-elastic supplementation products for joint

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Crosslinked hyaluronic acid implant for orthopaedics	Crespine Gel	Osteoarthritis of knee or hip	2 ml	III*
Crosslinked hyaluronic acid implant with prilocaine for orthopaedics	Crespine Gel +	Osteoarthritis of knee or hip	2 ml	III*

*In case of devices in Class III, this certificate independently does not authorize the manufacturer for the use of CE mark on the devices.

This certificate is valid only in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 134-CE-190327

Issue: 1
Issued: 27 April 2020
First issued: 27 April 2020
Start date of certified status: 22 March 2017

Valter PAPP, Dr.
General Manager

Expires:
25 May 2024

CE Certiso Ltd. NB2409 Notified Body

CE Certiso Ltd.
H-2092 Budakeszi, Erdő utca 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409