Notified Body 1023
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,**
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

# EC Certificate - Full Quality Assurance System
# No. 17 0266 QS/NB

The quality system of manufacturer

## Dr. Korman Laboratories Ltd.

**23, Yosef Levi str, Kiryat Bialik 2751123, Israel**

has been certified as meeting the requirements of

## Directive 93/42/EEC

**on medical devices, Annex II excluding (4)**

for the following product category(ies):

**Synovial fluid supplementation medium**

**Non-cross-linked hyaluronic acid fillers**

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

**Valid from:** 2020-05-22
**Valid until:** 2022-06-18
**First Issued:** 2017-06-19
**Revision:** c

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Date: 2020-05-22

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,**
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

# Annex to EC Certificate No. 17 0266 QS/NB

issued for manufacturer:

**Dr. Korman Laboratories Ltd.**
**23, Yosef Levi str, Kiryat Bialik 2751123, Israel**

## Product(s):

| | |
|---|---|
| **Name:** | **Intra-articular Hyaluronic Acid** |
| **Trade name(s):** | see table below |
| **Model(s):** | Concentration/Volume:<br>8 mg/ml / 1 ml syringe<br>16 mg/ml / 2 ml syringe<br>20 mg/ml / 2 ml syringe |
| **Class:** | III |
| **GMDN:** | 44757 |

The list of trade names:

| Product Name | Conc./Volume: 8 mg/ml / 1 ml syringe | Conc./Volume: 16 mg/ml / 2 ml syringe | Conc./Volume: 20 mg/ml / 2 ml syringe |
|---|---|---|---|
| Synovia | Mini | Forte | One |

Date: 2020-05-22
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