

## Declaration of Conformity

**Manufacturer:** Mylan Institutional, Coill Rua, Inverin, Co. Galway, Ireland,

| Products                            | Model No.'s | Item/Product Code | Classification:   |
|-------------------------------------|-------------|-------------------|---|
| Suplasyn <sup>®</sup>               | 0137        | FP-0137           | Class III as per<br>Rule 8 & Rule 17 of<br>Annex IX of MDD<br>93/42/EEC |
| Suplasyn <sup>®</sup> <i>m.d.</i>   | 0166        | FP-0166           |   |
| Suplasyn <sup>®</sup> <i>I-Shot</i> | 0203        | FP-0203           |   |
| GO-ON <sup>®</sup> one              |             |                   |   |

**Intended Purpose:**

Suplasyn, Suplasyn *I-Shot* & GO-ON<sup>®</sup> one are indicated for the symptomatic treatment of osteoarthritis. Suplasyn *m.d.* is indicated as a supplement for small synovial joints. The devices have been shown to be beneficial in osteoarthritis for the management of pain and improvement in physical function of joints.

**Notified Body (NB):** DEKRA Certification B.V. (DEKRA), NB number 0344.

**I herewith declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.**

The product described above is manufactured in a facility which has a quality management system certified to:

- ◆ **EN ISO 13485:2016** – Medical Devices – Quality Management System Requirements for Regulatory Purposes. Certificate No. 2189756.
- ◆ **Medical Devices Directives 93/42/EEC, Annex II** excluding (4) Full Quality Assurance System. Certificate No. 2199352CE01.

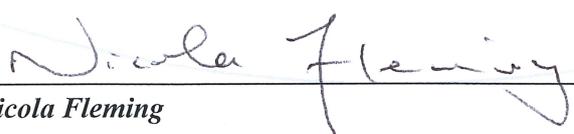
The design of the product described above is certified to:

- ◆ **Medical Devices Directives 93/42/EEC, Annex II (4)** – EC Design-Examination. Certificate No. 2199352DE02.

**Initial CE Certification Date:** 13<sup>th</sup> October 1998

**Date Effective:**

14<sup>th</sup> Jul 2025

  
**Nicola Fleming**  
 Senior Director of Quality  
 Mylan Institutional  
 Suplasyn

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