

EU Quality Management System Certificate BE25/00000310

The management system of

H&O Equipments NV/SA

The SGS logo is located in the top right corner. It consists of the letters 'SGS' in a bold, sans-serif font, with a vertical line to the right of the letters.

Rue des Journaliers 1, 7822 Ghislenghien (Ath), Belgium
SRN Number: BE-MF-000000992

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 08 December 2025 until 08 December 2030 and remains valid subject to satisfactory surveillance audits.

Recertification audit date due before 08 June 2030

Issue 1. Certified since 08 December 2025

A blue ink signature is located on the left side of the page, below the text 'Issue 1. Certified since 08 December 2025'.

Authorised by

Virginie Siloret

Head of Certification and
Compliance

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H&O Equipments NV/SA

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIa device

MDA0303

CryoPen/Freezpen:

Cryogenic surgical instrument and associated N2O gas cartridge intended for the treatment of benign skin lesions by dispensing a precise flow of nitrous oxide directly on the skin lesion

- CryoPen/Freezpen (B-UDI: 540700848SHOCPECLFP8G)
- N2O gas cartridge (B-UDI: 540700848SHON2OCLN2OUU)

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - BE/AND/210561 - S2A 1.2 + TFR 1.3

Authorized representative name and address (if relevant): N/A

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

