H&O EQUIPMENTS Reinventing Cryosurgery	Declaration of conformity CryoPen-CryoProbe M	D9.01.00
		Rev: 01

1. **Manufacturer**: H&O Equipments NV/SA
   Rue des Journaliers 1
   7822 Ghislenghien
   Belgium
2. **Products**: Cryogenic Surgical instruments
3. **Specified product:**

Description	Article Number
CryoPen M	S-HO-CMPE-XX-302 S-HO-CMPE-01
CryoProbe M	S-HO-CMPR-XX-902/903 S-HO-CMPR-01
Applicators for CryoPen M and CryoProbe M	S-HO-CCX0-MA-004/005/006 (-PR)
Cartridges 8g for Cryo M starter set	S-HO-8g-BOX
Cartridges 8g for CryoPen M Cartridges 8g for CryoProbe M	S-HO-NOCX-XX-S24/-12-S24 S-HO-NOCX-XX-S24-PR/-12-S24-PR

We declare under our sole responsibility that those products are in conformity with the essential requirements.

Document Nr.	Title	Date of emission	Risk Classification
93/42/EEC	Directive medical devices	14/06/1993	Class IIa (MDD, rule9)
DORS/98-282	Medical devices regulations	16/08/2012	Class II (MDR, rule9)

4. **Additional information:** (procedure of conformity, Notified Body, CE certificate, etc.)

- Procedure of conformity for CE marking: MDD, annexes II (excluding section 4)
- Notified Body: SGS House Noorderlaan 87 2030 Antwerp Belgium, number CE 1639, certificate Nr. BE19/819943764
- MDSAP/ISO 13485:2016 – SGS certificate BE20/819943916

Additional information for CryoProbe|m (for USA or Canada)

- Caution: Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner.
- Canadian License nr: 89787

Ghislenghien, Belgium
Date: 19/01/2023

Erik Hermans
Chief Executive Officer