H&O EQUIPMENTS Reinventing Cryosurgery	Declaration of conformity CryoPen-CryoProbe X+	D9.02.00
		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|x+	S-HO-CXPEP-01/02
CryoProbe|x+	S-HO-CXPRP-01/02
Applicator for CryoPen|x+ and CryoProbe|x+	S-HO-CCX0-MA-004/005/006/007 (-PR)
Long applicators 60mm	S-HO-CCX0-MA-008/009 (-PR)
Long applicator 120mm	S-HO-CCX0-MA-026
Cartridges 16g for Cryo X+ starter set	S-HO-16g-BOX
Cartridges 8g for CryoPen|x and CryoPen|x+	S-HO-NOCX-XX-S24/-12-S24
Cartridges 8g for CryoProbe|x and CryoProbe|x+	S-HO-NOCX-XX-S24-PR/-12-S24-PR
Cartridges 16g for CryoPen|x and CryoPen|x+	S-HO-NOCX-XL-S06/-12-S06
Cartridges 16g for CryoProbe|x and CryoProbe|x+	S-HO-NOCX-PRXL-S06/-PR-12-S06

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	02/03/2022	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 X+ (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