

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 XP	S-HO-CEPE-01
CryoProbe XP	S-HO-CEPR-01
Applicator for CryoPen XP and CryoProbe XP	S-HO-CCXP-MA-005/006/007/008
Cartridges 16g for Cryo XP starter sets	S-HO-16g-BOX
Cartridges 8g for CryoPen XP	S-HO-NOCX-XX-S24/-12-S24
Cartridges 8g for CryoProbe XP	S-HO-NOCX-XX-S24-PR/-12-S24-PR
Cartridges 16g for CryoPen XP	S-HO-NOCX-XL-S06/-12-S06
Cartridges 16g for CryoProbe XP	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	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 |XP (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