EC Certificate Full Quality Assurance System: BE19/819943709

The management system of

H&O Equipments NV/SA, also trading as 'Clinic6'

Rue des Journaliers 1
7822 Ghislenghien, Belgium

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 21 October 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 17 June 2022
Issue 1. Certified since 10 September 2004

Certification is based on reports numberedBE/AND 210561

Authorised by

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H&O Equipments NV/SA, also trading as 'Clinic6'

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 1

Detailed scope

Accurett: Cryogenic surgical instruments and associated CO2 gas cartridges intended for the treatment of superficial benign skin lesions:

- Viral warts (superficial)

- Molluscum contagiosum

- Seborrheic keratosis

- Solar keratosis

by dispensing a precise flow of carbon dioxide directly on the lesion.

CryoPen: Cryogenic surgical instruments and associated N2O gas cartridges intended for the treatment of pre-malignant skin lesions by dispensing a precise flow of nitrous oxide directly on the lesion.

Freezpen: Cryogenic surgical instruments and associated N2O gas cartridges intended for the treatment of pre-malignant skin lesions by dispensing a precise flow of nitrous oxide directly on the lesion.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market