EC Certificate Full Quality Assurance System: Certificate BE19/819943486

The management system of

Laboratoire Huckert's International srl

Avenue Lavoisier 20, 1300 Wavre, 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 May 2021 until 25 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 25 July 1999

Certification is based on reports numbered BE/AND 200467

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 **f** +32 (0)3 545-48-49 www.sgs.com

Laboratoire Huckert's International srl

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 4

Detailed scope

Concentrated UMONIUM38® dedicated to disinfection of invasive medical devices (Surgical instruments) and surface disinfection of non-invasive medical devices.

Ready to be used UMONIUM38® dedicated to disinfection of invasive medical devices (Surgical instruments) and surface disinfection of non-invasive medical devices.

Details

Surface disinfectants for non invasive medical devices
- Umonium 38 ® Equipments (125ml, 1L, 5L, 25L)
- Umonium 38 ® Medical Tissues (1, 10, 100, 95)
- Umonium 38 ® Neutralis tissue (1, 100, 95 wipes)

Disinfectants for invasive and non-invasive medical devices, with the exclusion of contact lenses

- U38 Instrument (125ml, 1L and 5L)
- U38 Instrument & Equipment (125ml, 1L and 5L)
- U38 Medical Spray (spray 250ml, 500ml and 1L)
- U38 Labocid (25L) - U38 Neutralis (125ml, 1L and 5L)
- U38 Neutralis Spray (250 and 500 ml)
- U38 Sterily (125ml, 1L and 5L

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.