



Certificate Number FI20/871769

The management system of

Serres Oy

Keskustie 23, Kauhajoki as, 61850, Finland

Dun & Bradstreet D-U-N-S identification number : 40-173-8638

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate



MDSAP (ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

Brazil:
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 /RDC ANVISA n. 67/2009

Canada:
Medical Devices Regulations – Part 1 SOR 98/282

Japan:
MHLW Ministerial Ordinance 169 /Article 4 to Article 68 / PMD Act

United States:
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

See second page for the scope.

The certificate is valid from
Effective Date: 2020-03-11 until Expiry Date: 2023-03-10
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2022-12-12
Issue 1. Certified since 2020-03-11

Authorised by J Hall
Business Manager

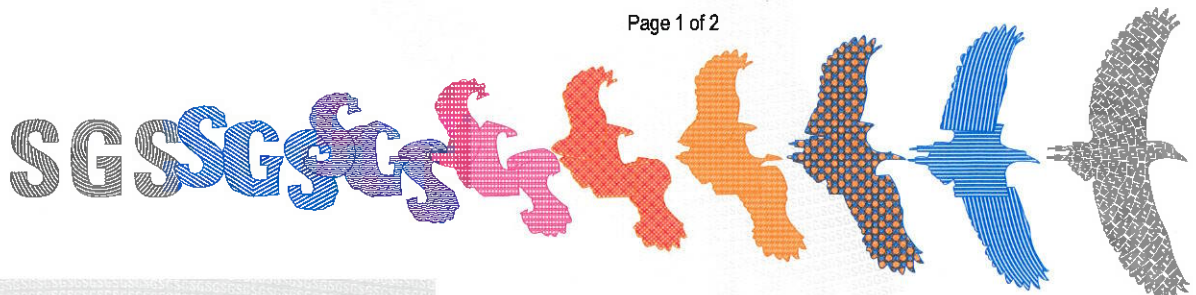


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MDSAP M2

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Certificate Number FI20/871769, continued

The management system of

Serres Oy

MDSAP (ISO 13485:2016)

Issue 1

Detailed scope

Design, Development and Manufacture of non-active suction bag systems for the areas of anaesthesiology, cardiovascular, dentistry, electrosurgical applications, ENT, gastroenterology, neurology, obstetrics & gynaecology, ophthalmology, orthopaedics, plastic surgery, radiology and urology

Additional facilities

Rentontie 3, Saarijärvi, 43100, Finland
Dun & Bradstreet D-U-N-S identification number : 53-804-4459

Manufacture of non-active suction bag systems for the areas of anaesthesiology, cardiovascular, dentistry, electrosurgical applications, ENT, gastroenterology, neurology, obstetrics & gynaecology, ophthalmology, orthopaedics, plastic surgery, radiology and urology

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM