

BUREAU VERITAS
Certification



Scanfil Oyj
Yritystie 6, FI-85410 Sievi, Finland

This is a multi-site certificate. Additional site details are listed in the appendix to this certificate.

Bureau Veritas Certification Denmark A/S certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below.

Standard

DS/EN ISO 13485:2016

Scope of certification

Contract based design, development, industrialization and manufacturing, logistic and post-delivery services of medical devices within electronics and mechanics.

Original cycle start date: **27-March-2017**
Expiry date of previous cycle: **NA**
Certification/Recertification Audit date: **NA**
Certification/ Recertification cycle start date: **27-March-2020**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **26-March-2023**

Certificate No.: DNKFRC102150 **Version:** 1 **Revision date:** 14-February-2020

Certification Office: **Bureau Veritas Certification Denmark A/S**
Oldenborggade 25-31, 7000 Fredericia, Denmark

Further clarifications regarding the scope of this certificate and the applicability of the Management System requirements may be obtained by consulting the organization. To check this certificate validity, please call **(+45) 77 311 000**. **1/3**





Scanfil Oyj

Standard

DS/EN ISO 13485:2016

Scope of certification

Contract based design, development, industrialization and manufacturing, logistic and post-delivery services of medical devices within electronics and mechanics.

<u>Site Name/location:</u>	<u>Site Addition Date:</u>	<u>Site Address:</u>	<u>Site Scope:</u>
Scanfil Oyj (Head Office)	27-03-2017	Yritystie 6, FI-85410 Sievi, Finland	Contract based design, development, industrialization and manufacturing, logistic and post-delivery services of medical devices within electronics and mechanics.
Scanfil EMS Oy	27-03-2017	Yritystie 6, FI-85410 Sievi, Finland	Contract based industrialization and manufacturing, logistic and post-delivery services of medical devices within electronics and mechanics.
Scanfil Åtvidaberg AB	27-03-2017	Örsätterfabriken, SE-597 80 Åtvidaberg, Sweden	Contract based design, development, industrialization and manufacturing, logistic and post-delivery services of medical devices within electronics and mechanics.
Scanfil Vellinge AB	27-03-2017	Bronsyxegatan 6B, SE-213 75 Malmö, Sweden	Contract based industrialization and manufacturing, logistic and post-delivery services of medical devices within electronics and mechanics.

Certificate No.: DNKFRC102150 Version: 1 Revision date: **14-February-2020**

Certification Office: *Bureau Veritas Certification Denmark A/S
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Scanfil Oyj

Standard

DS/EN ISO 13485:2016

Scope of certification

Scanfil Poland Sp. z o.o.	27-03-2017	Brzezińska 59, PL-41-404 Mysłowice, Poland	Contract based industrialization and manufacturing, logistic and post-delivery services of medical devices within electronics and mechanics.
Scanfil Poland Sp. z o.o., Oddział w Sieradzu	27-03-2017	Wojska Polskiego 107, PL-98-200 Sieradz, Poland	Contract based industrialization and manufacturing, logistic and post-delivery services of medical devices within electronics and mechanics.

Certificate No.: DNKFRC102150 Version: 1 Revision date: 14-February-2020

Certification Office: Bureau Veritas Certification Denmark A/S
Oldenborggade 25-31, 7000 Fredericia, Denmark

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DANAK
SYSTEM Reg nr. 5005