

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: 2 Revision date: **17-March-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

 **DANAK**
SYSTEM Reg.nr. 5005





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.

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Scanfil Oyj

Standard

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Scope of certification

Scanfil Poland Sp. z o.o.	27-03-2017	Brzezińska 59, PL-41-404 Myslowice, 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.
Scanfil Electronics GmbH	17-03-2020	Röberstr. 5, 99848 Wutha-Farnroda, Germany	Contract based industrialization and manufacturing, logistic and post-delivery services of medical devices within electronics and mechanics

Certificate No.: DNKFRC102150 Version: 2 Revision date: **17-March-2020**

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