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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*

**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:	<b>27-March-2017</b>
Expiry date of previous cycle:	<b>NA</b>
Certification/Recertification Audit date:	<b>NA</b>
Certification/ Recertification cycle start date:	<b>27-March-2023</b>

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **26-March-2026**

**Certificate No.: DNKFRC102230** Version: 1 Revision date: **15-February-2023**

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





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## Scanfil Oyj

*Standard*

# 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 Malmö AB	12-07-2022	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

# EN ISO 13485:2016

Scope of certification

<u>Site Name/location:</u>	<u>Site Addition Date:</u>	<u>Site Address:</u>	<u>Site Scope:</u>
Scanfil Poland Sp. z o.o. Myslowice	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.
Scanfil Atlanta	20-04-2021	4345 Hamilton Mill Road, suite 400, Buford, GA, 30518, Atlanta, USA	Contract based industrialization and manufacturing, logistic and post-delivery services of medical devices within electronics and mechanics.

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