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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*

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# EN ISO 13485:2016

*Scope of certification*

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**Contract-based design, development, industrialization and manufacturing, logistics, and post-delivery services of electronics, mechanics, product assemblies and medical devices for medical device industry.**

Original cycle start date:	<b>27-03-2017</b>
Expiry date of previous cycle:	<b>NA</b>
Certification/Recertification Audit date:	<b>NA</b>
Certification/Recertification cycle start date:	<b>27-03-2026</b>

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **26-03-2029**

**Certificate No.: DNKFRC102331** Version: **3** Revision date: **18-02-2026**

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**. 1/4





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# Scanfil Oyj

Standard

## EN ISO 13485:2016

Scope of certification

**Contract-based design, development, industrialization and manufacturing, logistics, and post-delivery services of electronics, mechanics, product assemblies and medical devices for medical device industry.**

<u>Site Name/location:</u>	<u>Site Address:</u>	<u>Site Scope:</u>
Scanfil Oyj (Head Office)	Yritystie 6, FI-85410 Sievi, FINLAND	Provision of centralized management controls for contract-based design, development, industrialization and manufacturing, logistics, and post-delivery services of electronics, mechanics, product assemblies and medical devices for medical device industry across multiple sites.
Scanfil EMS Oy	Yritystie 6, FI-85410 Sievi, FINLAND	Contract-based industrialization and manufacturing, logistics, and post-delivery services of electronics, mechanics, and product assemblies for medical device industry.
Scanfil Malmö AB	Bronsyxegatan 6B, SE-213 75 Malmö, SWEDEN	Contract-based industrialization and manufacturing, logistics, and post-delivery services of electronics, mechanics, and product assemblies for medical device industry.

**Certificate No.: DNKFRC102331 Version: 3 Revision date: 18-02-2026**

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



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# EN ISO 13485:2016

### Scope of certification

<u>Site Name/location:</u>	<u>Site Address:</u>	<u>Site Scope:</u>
Scanfil Åtvidaberg AB	Örsätterfabriken SE-597 94 Åtvidaberg, Örsätterfabriken SE-597 91 Åtvidaberg, SE-597 80 Åtvidaberg SWEDEN	Contract-based design, development, industrialization and manufacturing, logistics, and post-delivery services of electronics, mechanics, product assemblies and medical devices for medical device industry.
Scanfil Poland Sp. z o.o.	Brzezińska 59, PL-41-404 Mysłowice, POLAND	Contract-based industrialization and manufacturing, logistics, and post-delivery services of electronics, mechanics, and product assemblies for medical device industry.
Scanfil Poland Sp. z o.o. Oddział w Sieradzu	Wojska Polskiego 107, PL-98-200 Sieradz, POLAND	Contract-based industrialization and manufacturing, logistics, and post-delivery services of electronics, mechanics, and product assemblies for medical device industry.
Scanfil Electronics GmbH	Röberstr. 5, 99848 Wutha-Farnroda, GERMANY	Contract-based industrialization and manufacturing, logistics, and post-delivery services of electronics, mechanics, and product assemblies for medical device industry.

**Certificate No.: DNKFRC102331 Version: 3 Revision date: 18-02-2026**

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# Scanfil Oyj

Standard

## EN ISO 13485:2016

### Scope of certification

<u>Site Name/location:</u>	<u>Site Address:</u>	<u>Site Scope:</u>
Scanfil Inc.	4345 Hamilton Mill Road, Suite 400, Buford, GA 30518, Atlanta, USA	Contract-based industrialization and manufacturing, logistics, and post-delivery services of electronics, mechanics, and product assemblies for medical device industry.

Certificate No.: DNKFRC102331 Version: 3 Revision date: 18-02-2026

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



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