

**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-2017**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **26-March-2020**

**Certificate No.: DNKFRC101951** Version: 1 Revision date: **22-February-2019**

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**. 1/2

 **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 EMS Oy (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 Åtvidaberg AB	27-03-2017	Örsätterfabriken, SE-597 80 Åtvidaberg, Sweden	Contract based 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.
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.

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