Ilmoitettu laitos, Lääkinnälliset laitteet
Notified Body, Medical devices

Vaatimus/*Requirement* SFS-EN ISO/IEC 17065:2012
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AKKREDITOITU SERTIFIOINTIELIN

ACCREDITED CERTIFICATION BODY

FINAS
Finnish Accreditation Service
S063 (EN ISO/IEC 17065)

EUROFINS ELECTRIC & ELECTRONICS FINLAND OY

EUROFINS ELECTRIC & ELECTRONICS FINLAND LTD.

Tunnus ***Code***	**Yksikkö tai toimintoala** ***Department or section of activity***	**Osoite** ***Address***	**www**
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Tuotesertifiointi ***Product certification***
Ilmoitettu laitos, Lääkinnälliset laitteet ***Notified body, Medical devices***

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***			
Tekninen alue ***Technical area***	**Tuoteryhmä** ***Product category***	**Menettely/moduuli** ***Procedure/modul***	**Direktiivin artiklat /liitteet** ***Articles/annexes of the directive***
Ilmoitettu laitos, Lääkinnälliset laitteet (93/42/ETY) ***Notified Body, Medical devices (93/42/EEC)***			
Vaatimustenmukaisuuden arviointi lääkintälaitedirektiivin 93/42/ETY liitteiden II, V ja VI mukaisesti *Conformity assessment activities as defined in annexes II, V and VI of directive 93/42/EEC concerning medical devices*			
As from 26 May 2021, the Notified Body is no longer able to issue new certificates under Directive 93/42/EEC, but only allowed to carry out surveillance activities for certificates validly issued under that Directive in the transitional period, as established in Article 120 of Regulation 2017/745/EU.			

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
Ilmoitettu laitos, Lääkinnälliset laitteet, 2017/745/EU ***Notified Body, Medical devices, 2017/745/EU***		
Laki lääkinnällisistä laitteista 719/2021 ***The Act on Medical devices 719/2021, only in Finnish***		
2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on: product quality assurance	Annex XI(A)
2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on: product quality assurance	Annex XI(A)

PÄTEVYYSALUE *SCOPE OF ACCREDITATION*		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters Devices that directly contact central nervous system or central circulatory system, active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (e.g. closed loop systems or automated external defibrillators), and devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)
2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis Devices that directly contact central nervous system or central circulatory system, active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (e.g. closed loop systems or automated external defibrillators), and devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation Devices that directly contact central nervous system or central circulatory system, active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (e.g. closed loop systems or automated external defibrillators), and devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)
3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia Heater-cooler units (blood warmers) are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition Devices that directly contact central nervous system or central circulatory system, therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (e.g. closed loop systems or automated external defibrillators), and devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)
3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on: product quality assurance	Annex XI(A)
3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat Devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)
3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on: product quality assurance	Annex XI(A)

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices Devices that directly contact central nervous system or central circulatory system are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)
3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport Active prostheses and exoskeletons are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)
3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software Software intended to provide information, which is used to take decisions having an impact that may cause death or an irreversible deterioration of a person's state of health, and therapeutic devices with an integrated or incorporated diagnostic function, which significantly determines the patient management by the device e.g. closed loop systems or automated external defibrillators, are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilization Devices for sterilization are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)
3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on: product quality assurance	Annex XI(A)
1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants Other devices except sutures, staples, screws, wedges, plates, wires, pins, clips and connectors are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)
2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on: product quality assurance	Annex XI(A)
2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis Devices for dialysis are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)
2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on: product quality assurance	Annex XI(A)

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices Contact lenses and intraocular lenses are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)
2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on: product quality assurance	Annex XI(A)
2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on: product quality assurance	Annex XI(A)
2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on: product quality assurance	Annex XI(A)
2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on: product quality assurance	Annex XI(A)
2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route Devices (or their products of metabolism) that are systemically absorbed by the human body are excluded.	Conformity assessment based on: product quality assurance	Annex XI(A)
2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on: product quality assurance	Annex XI(A)

PÄTEVYYSALUE *SCOPE OF ACCREDITATION*		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
Akkreditoidulla toimijalla on ilmoitetun laitoksen toimintaa tämän asetuksen osalta myös muissa pätevyysalueissa. Pätevyysalueet julkaistaan FINAS akkreditointipalvelun verkkosivuilla. *CAB has accredited activity under this regulation also in other scopes of accreditation. Scopes are published on the FINAS website.*		

PÄTEVYYSALUE *SCOPE OF ACCREDITATION*			
Tekninen alue ***Technical area***	**Tuoteryhmä** ***Product category***	**Menettely/moduuli** ***Procedure/modul***	**Direktiivin artiklat /liitteet** ***Articles/annexes of the directive***
In vitro-diagnostiikkaan tarkoitetuista lääkinnällisistä laitteista annetun direktiivin 98/79/EY mukaisen ilmoitetun laitoksen toiminta ***The operation of the Notified Body as defined in directive 98/79/EC on in vitro diagnostic medical devices***			
Vaatimustenmukaisuuden arviointi lääkintälaitedirektiivin 98/79/EY liitteen IV mukaisesti ***Conformity assessment activities as defined in annex IV of directive 98/79/EC on in vitro diagnostic medical devices***			
List A: Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of marker of	*HIV infection (HIV 1 and 2)*	Moduuli H Suunnittelun tarkastus *Module H: EC design examination*	Liite IV k. 4 ja 6 *Annex IV p. 4 and 6*
	HTLV I and II		
	Hepatitis B, C, D		
In vitro-diagnostiikkaan tarkoitetuista lääkinnällisistä laitteista annetun direktiivin 98/79/EY mukaisen ilmoitetun laitoksen toiminta ***The operation of the Notified Body as defined in directive 98/79/EC on in vitro diagnostic medical devices***			
Vaatimustenmukaisuuden arviointi lääkintälaitedirektiivin 98/79/EY liitteiden III ja IV mukaisesti ***Conformity assessment activities as defined in annexes III and IV of directive 98/79/EC on in vitro diagnostic medical devices***			
Devices for self-testing	*Clinical chemistry*	Moduuli A: Suunnittelun arviointi *Module A: Design examination*	Liite III *Annex III*

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***			
Tekninen alue ***Technical area***	**Tuoteryhmä** ***Product category***	**Menettely/moduuli** ***Procedure/modul***	**Direktiivin artiklat /liitteet** ***Articles/annexes of the directive***
	Immunology		
	Molecular biology		
	Pregnancy and ovulation		
	Specimen receptables		
In vitro-diagnostiikkaan tarkoitetuista lääkinnällisistä laitteista annetun direktiivin 98/79/EY mukaisen ilmoitetun laitoksen toiminta ***The operation of the Notified Body as defined in directive 98/79/EC on in vitro diagnostic medical devices***			
IVD Specifics	*IVDs incorporating software / utilising software / controlled by software*	Moduuli A: Suunnittelun arviointi *Module A: Design examination*	Liite III *Annex III*
	IVDs utilising material of human origin		