AKKREDITOITU SERTIFIOINTIELIN

ACCREDITED CERTIFICATION BODY

FINAS
Finnish Accreditation Service
S021 (EN ISO/IEC 17021-1)

EUROFINS ELECTRIC & ELECTRONICS FINLAND OY

Tunnus ***Code***	**Sertifiointielin** ***Certification body***	**Osoite** ***Address***	**www** ***www***
S021	**Eurofins Electric & Electronics Finland Oy** ***Eurofins Electric & Electronics Finland Oy***	**Hermiankatu 6-8 H** **33720 Tampere** ***Hermiankatu 6-8 H*** ***FI- 33720 Tampere*** ***FINLAND***	**www.eurofins.fi/electrical-and-electronics**

Järjestelmäsertifiointi ***Certification of management systems***
Laatujärjestelmät (ISO 9001) ***Quality Management Systems (ISO 9001)***
Työterveys- ja työturvallisuusjärjestelmät (ISO 45001) ***Occupational health and safety management systems (ISO 45001)***
Ympäristöjärjestelmät (ISO 14001) ***Environmental Management Systems (ISO 14001)***
Laadunhallintajärjestelmät terveydenhuollon laitteiden ja tarvikkeiden alueella (ISO 13485) ***Quality Management Systems in the field of Medical devices and equipment (ISO 13485)***

Ilmoitettu laitos ***Notified body***
Ilmoitettu laitos, Lääkinnälliset laitteet ***Notified Body, Medical devices***

Ilmoitettu laitos, In vitro lääkinnälliset laitteet
Notified Body, In vitro medical devices

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***	
Sertifiointikohde ***Certification category***	**Toimiala (EA-, NACE-koodi)** ***Technical area (EA-, NACE-code)***
Järjestelmäsertifiointi ***Certification of management systems***	
Laatujärjestelmien sertifiointi standardin SFS-EN ISO 9001:2015 perusteella ***Certification of Quality Management Systems to SFS-EN ISO 9001:2015***	
Työterveys- ja työturvallisuusjärjestelmien sertifiointi ISO 45001:2018 (SFS-EN ISO 45001:2023) perusteella ***Certification of occupational health and safety management systems to ISO 45001:2018 (SFS-EN ISO 45001:2023)***	
	3 **C 10, 11** Elintarvikkeiden ja juomien valmistus *Manufacture of food products, Manufacture of beverages*
	4 **C 14** Tekstiilituotteiden valmistus *Manufacture of wearing apparel*
	6 **C 16** Sahatavaran sekä puu- ja korkkituotteiden valmistus (pl. huonekalut; olki- ja punontatuotteiden valmistus) *Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials*
	12 **C 20** Kemikaalien ja kemiallisten tuotteiden valmistus *Manufacture of chemicals and chemical products*
	14 **C 22** Kumi- ja muovituotteiden valmistus *Manufacture of rubber and plastic products*
	15 **C 23** Muiden ei-metallisten mineraalituotteiden valmistus *Manufacture of other non-metallic mineral products*
	16 **C 23.6** Betoni-, kipsi- ja sementtituotteiden valmistus *Manufacture of articles of concrete, cement and plaster*

PÄTEVYYSALUE *SCOPE OF ACCREDITATION*		
Sertifiointikohde *Certification category*	**Toimiala (EA-, NACE-koodi)** *Technical area (EA-, NACE-code)*	
	17	**C 24** (poislukien/*excluding* C 24.4.6) Metallien jalostus (pl. Ydinpolttoaineen valmistus) *Manufacture of basic metals (except processing of nuclear fuel)* **C 25** (poislukien/*excluding* C 25.4) Metallituotteiden valmistus (pl. Koneet ja laitteet, Aseiden ja ammusten valmistus) *Manufacture of fabricated metal products (except machinery and equipment and manufacture of weapons and ammunition)* **C 33.1** Metallituotteiden, teollisuuden koneiden ja laitteiden korjaus ja huolto *Repair of fabricated metal products, machinery and equipment*
	18	**C 25.4, C 28, C 33.2** Aseiden ja ammusten valmistus *Manufacture of weapons* Muiden koneiden ja laitteiden valmistus *Manufacture of machinery and equipment n.e.c.* Teollisuuslaitteiden asentaminen *Installation of industrial machinery and equipment*
	19	**C 26, C 27** Tietokoneiden sekä elektronisten ja optisten tuotteiden ja sähkölaitteiden valmistus *Manufacture of computer, electronic, optical products and electrical equipment*
	22	**C 29** Moottoriajoneuvojen, perävaunujen ja puoliperävaunujen valmistus *Manufacture of motor vehicles, trailers and semi-trailers*
	23	**C 32.5** Lääkintä- ja hammaslääkintäinstrumenttien ja –tarvikkeiden valmistus *Manufacture of medical and dental instruments and supplies*
	25	**D 35.1** Sähkövoiman tuotanto, siirto ja jakelu *Electric power generation, transmission and distribution*
	28	**F 41, F 42, F 43** Talonrakentaminen, maa ja vesirakentaminen ja erikoistunut rakennustoiminta *Construction of buildings, civil engineering and specialised construction activities*

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***		
Sertifiointikohde ***Certification category***	**Toimiala (EA-, NACE-koodi)** ***Technical area (EA-, NACE-code)***	
	29	**G 45, G 46** Moottoriajoneuvojen ja moottoripyörien tukku- ja vähittäiskauppa sekä korjaus *Wholesale and retail trade and repair of motor vehicles and motorcycles* Tukkukauppa, poislukien moottoriajoneuvojen ja moottoripyörien kauppa *Wholesale trade, except of motor vehicles and motorcycles*
	31	**H 52** Varastointi ja liikennettä palveleva toiminta *Warehousing and support activities for transportation*
	33	**J 62, J 63.1** Atk-laitteisto- ja ohjelmistokonsultointi, tietojenkäsittely, palvelintilan vuokraus ja niihin liittyvät palvelut; verkkoportaalit *Computer programming, consultancy and related activities, data processing, hosting and related activities; web portals*
	34	**M 71, M 72** Arkkitehti- ja insinööripalvelut; tekninen testaus ja analysointi *Architectural and engineering activities; technical testing and analysis* Tieteellinen tutkimus ja kehittäminen *Scientific research and development*
	35	**M 70.2, M 82** Liikkeenjohdon konsultointi, hallinto- ja tukipalvelut liike-elämälle *Other management consultancy activities, other business support activities*
	36	**O 84.1** Julkinen hallinto *Public administration*
	37	**P 85** Koulutus *Education*
	38	**Q 86.9** Muut terveydenhuoltopalvelut *Other human health activities*

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***	
Sertifiointikohde ***Certification category***	**Toimiala (EA-, NACE-koodi)** ***Technical area (EA-, NACE-code)***
	39 **E 38.1, E 38.2** Jätteen keruu, käsittely ja loppusijoitus; materiaalien kierrätys (koskien ainoastaan sähkö- ja elektroniikkaromua) *Waste collection, treatment and disposal activities; materials recovery (regarding only electric and electronic waste)* **E 38.11** Tavanomaisen jätteen keräily *Collection of non-hazardous waste* **E 93.29** Muu huvi- ja virkistystoiminta *Other amusement and recreation activities* **S 94.6** Yhdistystoiminta *Activities of other membership organisations* **S 96.01** Pesulapalvelut *Washing and (dry-)cleaning of textile and fur products*

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***		
Sertifiointikohde ***Certification category***	**Toimiala (NACE-koodi)** ***Technical area (NACE-code)***	
Ympäristöjärjestelmien sertifiointi standardin SFS-EN ISO 14001:2015 perusteella ***Certification of environmental management systems to SFS-EN ISO 14001:2015***		
	C	**TEOLLISUUS** ***MANUFACTURING***
	10	Elintarvikkeiden valmistus *Manufacture of food products*
	11	Juomien valmistus *Manufacture of beverages*
	14	Tekstiilituotteiden valmistus *Manufacture of wearing apparel*
	16	Sahatavaran sekä puu- ja korkkituotteiden valmistus (pl. huonekalut; olki- ja punontatuotteiden valmistus) *Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials*

PÄTEVYYSALUE *SCOPE OF ACCREDITATION*		
Sertifiointikohde *Certification category*	**Toimiala (NACE-koodi)** *Technical area (NACE-code)*	
	20	Kemikaalien ja kemiallisten tuotteiden valmistus *Manufacture of chemicals and chemical products*
	22	Kumi- ja muovituotteiden valmistus *Manufacture of rubber and plastic products*
	23	Muiden ei-metallisten mineraalituotteiden valmistus *Manufacture of other non-metallic mineral products*
	24	Metallien jalostus (pl. Ydinpolttoaineen valmistus 24.4.6) *Manufacture of basic metals (except processing of nuclear fuel 24.4.6)*
	25	Metallituotteiden valmistus (pl. koneet ja laitteet) *Manufacture of fabricated metal products, except machinery and equipment*
	26	Tietokoneiden sekä elektronisten ja optisten tuotteiden ja sähkölaitteiden, lääkintä- ja hammaslääkintäinstrumenttien ja –tarvikkeiden valmistus *Manufacture of computer, electronic and optical products*
	27	Sähkölaitteiden valmistus *Manufacture of electrical equipment*
	28	Muiden koneiden ja laitteiden valmistus *Manufacture of machinery and equipment n.e.c.*
	29	Moottoriajoneuvojen, perävaunujen ja puoliperävaunujen valmistus *Manufacture of motor vehicles, trailers and semi-trailers*
	32.5	Lääkintä- ja hammaslääkintäinstrumenttien ja –tarvikkeiden valmistus *Manufacture of medical and dental instruments and supplies*
	33.1	Metallituotteiden korjaus *Repair of fabricated metal products, machinery and equipment*
	33.2	Teollisuuslaitteiden asentaminen *Installation of industrial machinery and equipment*
	D	SÄHKÖ-, KAASU-, LÄMPÖ- JA ILMASTOINTIHUOLTO *ELECTRICITY, GAS, STEAM AND AIR CONDITIONING SUPPLY*

PÄTEVYYSALUE *SCOPE OF ACCREDITATION*		
Sertifiointikohde *Certification category*	**Toimiala (NACE-koodi)** *Technical area (NACE-code)*	
	35.1	Sähkövoiman tuotanto, siirto ja jakelu *Electric power generation, transmission and distribution*
	E	VESIHUOLTO, VIEMÄRI- JA JÄTEVESIHUOLTO, JÄTEHUOLTO JA MUU YMPÄRISTÖN PUHTAANAPITO *WATER SUPPLY; SEWERAGE, WASTE MANAGEMENT AND REMEDIATION ACTIVITIES*
	38.1, 38.2	Jätteen keruu, käsittely ja loppusijoitus; materiaalien kierrätys (koskien ainoastaan sähkö- ja elektroniikkajätettä) *Waste collection, treatment and disposal activities; materials recovery (regarding only electrical and electronic waste)*
	38.11	Tavanomaisen jätteen keräily *Collection of non-hazardous waste*
	F	RAKENTAMINEN
	41, 42, 43	Talonrakentaminen, maa- ja vesirakentaminen ja erikoistunut rakennustoiminta Construction of buildings, civil engineering, specialised construction activities
	G	TUKKU JA VÄHITTÄISKAUPPA; MOOTTORIAJONEUVOJEN JA MOOTTORIPYÖRIEN KORJAUS *WHOLESALE AND RETAIL TRADE; REPAIR OF MOTOR VEHICLES AND MOTORCYCLES*
	45	Moottoriajoneuvojen ja moottoripyörien tukku- ja vähittäiskauppa sekä korjaus *Wholesale and retail trade and repair of motor vehicles and motorcycles*
	46	Tukkukauppa, poislukien moottoriajoneuvojen ja moottoripyörien kauppa *Wholesale trade, except of motor vehicles and motorcycles*
	H	KULJETUS JA VARASTOINTI *TRANSPORTATION AND STORAGE*
	52	Varastointi ja liikennettä palveleva toiminta *Warehousing and support activities for transportation*
	J	INFORMAATIO JA VIESTINTÄ *INFORMATION AND COMMUNICATION*

PÄTEVYYSALUE *SCOPE OF ACCREDITATION*		
Sertifiointikohde *Certification category*	**Toimiala (NACE-koodi)** *Technical area (NACE-code)*	
	62, 63.1	Atk-laitteisto- ja ohjelmistokonsultointi, tietojenkäsittely, palvelintilan vuokraus ja niihin liittyvät palvelut; verkkoportaalit *Computer programming, consultancy and related activities, data processing, hosting and related activities; web portals*
	M	AMMATILLINEN, TIETEELLINEN JA TEKNINEN TOIMINTA *PROFESSIONAL, SCIENTIFIC AND TECHNICAL ACTIVITIES*
	70.2, 82	Muu liikkeenjohdon konsultointi, muu liike-elämää palveleva toiminto *Other management consultancy activities, other business support activities*
	71	Arkkitehti- ja insinööripalvelut; tekninen testaus ja analysointi *Architectural and engineering activities; technical testing and analysis*
	O	JULKINEN HALLINTO JA MAANPUOLUSTUS *PUBLIC ADMINISTRATION AND DEFENCE*
	84.1	Julkinen hallinto *Administration of the state and the economic and social policy of the community*
	P	KOULUTUS *EDUCATION*
	85	Koulutus *Education*
	Q	TERVEYS- JA SOSIAALIPALVELUT *HUMAN HEALTH AND SOCIAL WORK ACTIVITIES*
	86.9	Muut terveydenhuoltopalvelut *Other human health activities*
	R	TAITEET, VIIHDE JA VIRKISTYS *ARTS, ENTERTAINMENT AND RECREATION*
	93.29	Muu huvi- ja virkistystoiminta *Other amusement and recreation activities*
	S	MUU PALVELUTOIMINTA *OTHER SERVICE ACTIVITIES*
	94.6	Yhdistystoiminta *Activities of other membership organisations*

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***		
Sertifiointikohde ***Certification category***	**Toimiala (NACE-koodi)** ***Technical area (NACE-code)***	
	96.01	Pesulapalvelut *Washing and (dry-)cleaning of textile and fur products*

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***	
Tekninen pääalue ***Main technical area***	**Tekninen alue** ***Technical area***
Laatujärjestelmien sertifiointi terveydenhuollon laitteiden ja tarvikkeiden alueella standardin SFS-EN ISO 13485:2016 perusteella ***Certification of Quality Management Systems in the field of Medical devices to standard SFS-EN ISO 13485:2016***	
General non-active, non-implantable medical devices	Non-active devices for anaesthesia, emergency and intensive care
	Non-active devices for injection, infusion, transfusion and dialysis
	Non-active orthopaedic and rehabilitation devices
	Non-active medical devices with measuring function
	Non-active ophthalmologic devices
	Non-active instruments
	Non-active medical devices for disinfecting, cleaning, rinsing
	Non-active medical devices for ingestion
Non-active implants	Non-active orthopaedic implants
Devices for wound care	Bandages and wound dressings
	Other medical devices for wound care
Non-active dental devices and accessories	Non-active dental equipment and instruments
	Dental materials
	Dental implants
Non-active medical devices other than specified above	
General active medical devices	Devices for stimulation or inhibition
	Active surgical devices
	Active ophthalmologic devices
	Active dental devices
	Active devices for disinfection and sterilisation
	Active rehabilitation devices and active prostheses
	Software

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***	
Tekninen pääalue ***Main technical area***	**Tekninen alue** ***Technical area***
Devices for imaging	Imaging devices utilising ionizing radiation
	Imaging devices utilising non-ionizing radiation
Monitoring devices	Monitoring devices of non-vital physiological parameters
	Monitoring devices of vital physiological parameters
Devices for radiation therapy and thermo therapy	Devices utilising non-ionizing radiation
	Devices for hyperthermia / hypothermia
Active (non-implantable) medical devices other than specified above	
Specifics of medical devises	Medical devices referencing the Directive 2006/42/EC on machinery
	Medical devices in sterile condition
	Medical devices incorporating software/utilising software/controlled by software
In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry; Immunochemistry (Immunology); Haematology/Haemostasis/Immunohematology; Microbiology; Infectious Immunology; Histology/Cytology; Genetic Testing
	In Vitro Diagnostic Instruments and software
	Sample containers
Sterilisation Method for Medical devices	Aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, dry heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)

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 mukainen toiminta *Conformity assessment activities as defined in annexes II, V ja 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 **Kansallinen lainsäädäntö, laki 719/2021** ***Notified Body, Medical devices, 2017/745/EU*** ***National legislation, law 719/2021***		
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: quality management system	Annex IX(I)
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: quality management system	Annex IX(I)

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: quality management system	Annex IX(I)
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: quality management system	Annex IX(I)

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: quality management system	Annex IX(I)
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: quality management system	Annex IX(I)
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: quality management system	Annex IX(I)
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: quality management system	Annex IX(I)

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 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: quality management system	Annex IX(I)
3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on: quality management system	Annex IX(I)
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: quality management system	Annex IX(I)
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: quality management system	Annex IX(I)
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: quality management system	Annex IX(I)

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: quality management system	Annex IX(I)
3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on: quality management system	Annex IX(I)
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: quality management system	Annex IX(I)
2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on: quality management system	Annex IX(I)
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: quality management system	Annex IX(I)
2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on: quality management system	Annex IX(I)
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: quality management system	Annex IX(I)

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 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on: quality management system	Annex IX(I)
2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on: quality management system	Annex IX(I)
2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on: quality management system	Annex IX(I)
2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on: quality management system	Annex IX(I)
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: quality management system	Annex IX(I)
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: quality management system	Annex IX(I)
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.*		

Ilmoitettu laitos, in vitro diagnostiset lääkinnälliset laitteet (98/79/EY)
Notified Body, in vitro diagnostic medical devices (98/79/EC)

Vaatimustenmukaisuuden arviointi in vitro diagnostisten lääkintälaitedirektiivin 98/79/EY liitteiden III ja IV mukainen toiminta *Conformity assessment activities as defined in annexes III ja IV of directive 98/79/EC concerning in vitro diagnostic medical devices*
As from 26 May 2022, the Notified Body is no longer able to issue new certificates under Directive 98/79/EC, but only allowed to carry out surveillance activities for certificates validly issued under that Directive in the transitional period, as established in Article 110 of Regulation 2017/746/EU.

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
Ilmoitettu laitos, In vitro lääkinnälliset laitteet, 2017/746/EU **Kansallinen lainsäädäntö, laki laki 719/2021 ja 629/2010** ***Notified Body, In vitro medical devices, 2017/746/EU*** ***National legislation law 719/2021 and 629/2010***		
3. Devices intended to be used for markers of cancer and non-malignant tumours IVR 0301 Devices intended to be used in screening, diagnosis, staging or monitoring of cancer Excluding epigenetics	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
3. Devices intended to be used for markers of cancer and non-malignant tumours IVR 0302 Other devices intended to be used for markers of cancer and non-malignant tumours Excluding epigenetics	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
4. Devices intended to be used for human genetic testing IVR 0401 Devices intended to be used in screening/confirmation of congenital/inherited disorders Excluding epigenetics and large-scale human exome analyses	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)

PÄTEVYYSALUE *SCOPE OF ACCREDITATION*		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
4. Devices intended to be used for human genetic testing IVR 0402 Devices intended to be used to predict genetic disease/disorder risk and prognosis Excluding epigenetics and large-scale human exome analyses	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
4. Devices intended to be used for human genetic testing IVR 0403 Other devices intended to be used for human genetic testing Excluding epigenetics and large-scale human exome analyses	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
5. Devices intended to be used to determine markers of infections/immune status IVR 0501 Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
5. Devices intended to be used to determine markers of infections/immune status IVR 0502 Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)

PÄTEVYYSALUE *SCOPE OF ACCREDITATION*		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
5. Devices intended to be used to determine markers of infections/immune status IVR 0503 Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
5. Devices intended to be used to determine markers of infections/immune status IVR 0504 Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
5. Devices intended to be used to determine markers of infections/immune status IVR 0505 Devices intended to be used to grow/isolate/identify and handle infectious agents	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
5. Devices intended to be used to determine markers of infections/immune status IVR 0506 Other devices intended to be used to determine markers of infections/immune status	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures IVR 0601 Devices intended to be used for screening/confirmation of specific disorders/impairments	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)

PÄTEVYYSALUE *SCOPE OF ACCREDITATION*		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures IVR 0602 Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures IVR 0603 Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures IVR 0604 Other devices intended to be used for a specific disease	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures IVR 0605 Devices intended to be used for monitoring of levels of medicinal products, substances or biological components	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)

PÄTEVYYSALUE *SCOPE OF ACCREDITATION*		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures IVR 0606 Devices intended to be used for non-infectious disease staging	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
6. Devices intended to be usedfor non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures IVR 0607 Devices intended to be used for detection of pregnancy or fertility testing	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures IVR 0608 Devices intended to be used for screening, determination or monitoring of physiological markers	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures IVR 0609 Other devices intended to be used to define or monitor physiological status and therapeutic measures	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)
7. Devices which are controls without a quantitative or qualitative assigned value IVR 0701 Devices which are controls without a quantitative assigned value	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)

PÄTEVYYSALUE ***SCOPE OF ACCREDITATION***		
Tuote/tuotevalikoima ***Product/product range***	**Menettely/moduuli** ***Procedure/Module***	**Asetuksen artiklat/liitteet** ***Articles/annexes of the regulation***
7. Devices which are controls without a quantitative or qualitative assigned value IVR 0702 Devices which are controls without a qualitative assigned value	*Conformity assessment based on a quality management system* *Conformity assessment based on assessment of technical documentation*	Annex IX(I) Annex IX(II)