TÜVNORD

Passion
for Safety

Medical Device Regulation

(EU)2017/745

TÜV NORD Korea

tuev-nord.de

TÜV®

TÜVNORDGROUP

TÜV NORD 에서는 보다 빠르고 안전하게 MDR 인증을 취득하실 수 있습니다.

We are Team NB

유럽의 TEAM NB 에 등록되어 MDR 인증을 수행할 수 있는 인증기관 (NB-Notified body)은 현재 35곳 입니다. 이 중 TÜV NORD 는 TÜV NORD Germany & Poland 두 곳이 NB로 지정되어있습니다.

2 NB : TÜV NORD Germany & Poland

TÜV NORD Poland 에서는 2022년 5월 NB 지정 후 2023년 3월까지 총 9개의 인증서가 발행되었습니다. 전세계 평균 MDR 인증소요기간은 12~18개월임을 감안할 때 TÜV NORD 에서는 보다 빠르게 MDR 인증을 받을 수 있음을 의미합니다.

TÜV NORD Korea

MDR 가능 NB 중 한국 지사가 있어 커뮤니케이션을 원활하게 지원할 수 있는 곳은 10곳 미만입니다. TÜV NORD Korea 에서는 고객과 TÜV NORD Poland, Germany 두 NB간의 커뮤니케이션을 돕습니다.

Your benefit Why TÜV NORD?

빠르고 쉽게

TÜV NORD 에서는 신청서 제출 후 바로 Application Review 에 착수합니다. 인증 단계가 다른 NB보다 1단계 단축되어 보다 빠르게 MDR 인증을 받으실 수 있습니다.

30년 경험의 전문성

TÜV NORD 는 의료기기 인증 분야에서 30년 이상의 경험을 가진 기관으로, 다양한 종류의 의료기기 인증과 관련된 전문성과 경험을 보유하고 있습니다.

글로벌 인정

TÜV NORD 는 유럽 뿐만 아니라 세계적으로도 인정받는 인증기관으로, 전 세계 100여개 국가에서 활동하며 다양한 의료기기 제조업체와 협력하고 있습니다.

적극적인 고객 지원

인증을 받는 의료기기 제조업체와 적극적으로 협력하여 인증 프로세스를 원활하게 진행하도록 지원하며, 인증 후에도 꾸준한 고객 지원을 제공합니다.

About TÜV NORD?

100
Active in 100 countries

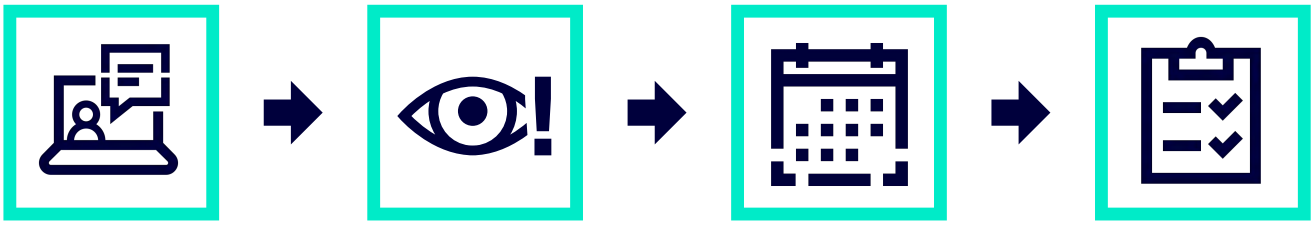
14,000
Employees worldwide

1.45 billion €
Sales 2022

TÜV NORD Korea

MDR certification procedure?

Your route to MDR certification in 8 steps:

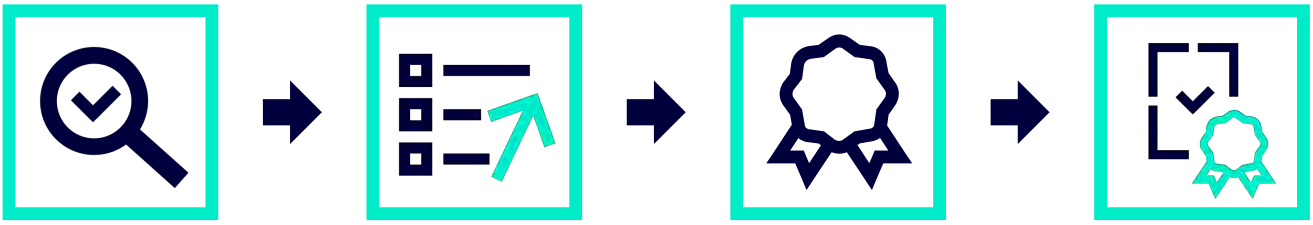


인증신청

기술문서, 품질매뉴얼 Application 제출

제출된 문서 검토 후 심사 일정 제안 및 견적서, 계획 송부

기술 및 임상 문서 평가



품질경영시스템 심사
- (특정 등급의 경우) 임상 협의
- SSCP(Summary of safety and clinical performance) 유효성 검사

TD 및 QM 부적합 관리

인증서 발행여부 결정

인증서 발행 및 EUDAMED database 등재

인증서 발행 이후: 시판 후 조사 (Post-Market Surveillance) **및 제품 업데이트 등, 필요한 경우 TD 평가 및 심사 프로그램 조정**

From MDD to MDR

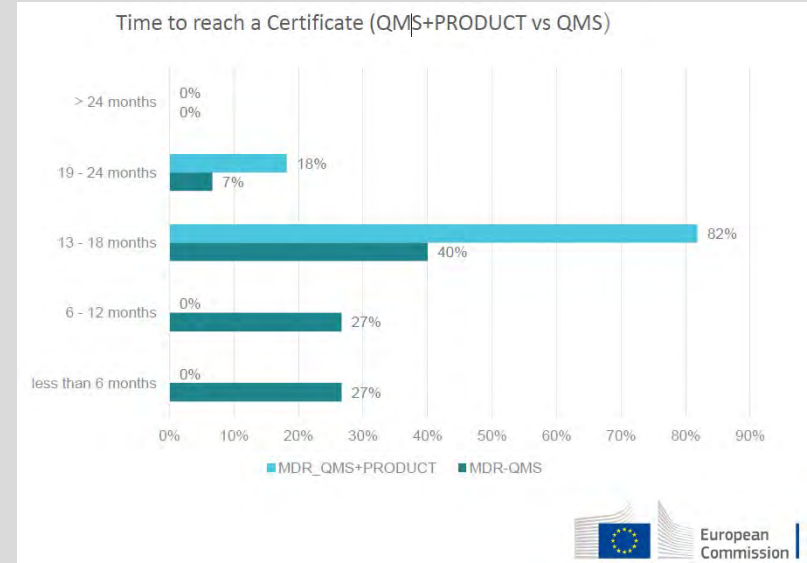
Check on YouTube video clip - 재생버튼을 클릭하세요!

F&Q

MDR 인증을 받는데 소요되는 기간이 궁금합니다

(올해 빠르게 신청하신다면) TÜV NORD에서는 1년 내에 인증서 취득이 가능합니다.

- EU 집행위원회에서 공식 발표한 통계에 따르면 (우측도표 참조) 통상적으로 MDR 인증에는 통상적으로13~18개월이 소요됩니다.
- TÜV NORD Poland 와 인증을 진행하시는 경우엔 최대 12개월 이내에 인증서 취득이 가능합니다.
- TÜV NORD Poland 에서는 2022년 5월 NB 지정 후, 2023년 3월 현재까지 9개의 MDR 인증서를 발행했습니다. 이는 신청서 접수 즉시 검토 작업에 착수하기 때문에 가능한 성과입니다.
- TÜV NORD Poland 는 인증서 발행기간의 단축을 위해 설문서 작성 단계를 생략하였으며, 이는 타 NB보다 프로세스가 한단계 단축되었음을 의미합니다.
- 설문서 단계가 있는 타 NB의 경우, 견적서를 받고 Application, 기술문서, 품질 매뉴얼을 제출한 Application 검토를 위해 또 다른 수개월을 기다려야할 수 있습니다.
- TÜV NORD Poland 에서는 Application Review비용 견적서 수령 후 3개월 이내에 심사를 시작할수 있습니다.
  ·Application Review는 Application, 기술문서, 품질 매뉴얼을 포함하며, 모든 문서 제출 이후엔 검토 진행을 위해 Application Review 비용(1,000EUR)이 청구됩니다.



Source : European Commission 'Notified Bodies Survey on certifications and applications

MDD 인증을 TÜV NORD 에서 받지 않았어도 빠르게 MDR 인증을 받을 수 있나요?

기존에 TÜV NORD에서 MDD 인증을 받지 않으셨더라도 TÜV NORD에서 빠르게 MDR 인증을 받으실 수 있습니다.

- 다른 NB의 경우, 기존 MDD 고객을 위주로 MDR 전환을 진행하고 있어 신규 업체를 받지 않는 경우가 있고, 받더라도 신규 고객은 후순위로 밀리는 경우가 많아 심사를 시작하는데까지 1년 이상 소요되는 곳도 많을 것입니다.
- TÜV NORD Poland는 한단계 단축된 인증 프로세스를 통해 제출부터 인증서 발행까지 약 9개월에서 12개월 정도가 소요되며, 기존 고객이 아니라 인증 받을 준비가 된 고객을 우선으로 합니다.
- 이런 점을 고려했을 때, TÜV NORD Poland는 신규 고객이 심사를 가장 빠르게 시작할 수 있는 최선의 선택이 될 것입니다.

F&Q

TÜV NORD 에서 제공하는 MDR 관련 교육 또는 참고할만한 자료가 있나요?

TÜV NORD Poland 에서 자체 MDR E-Learning Training을 통해 관련 교육(MDR 개괄 및 ISO 13485 요구사항 전반)을 제공하고 있습니다. (2주 분량, 영어, 단체 할인)

기술문서와 품질 매뉴얼 모두 준비되어 있어야 하나요?

기술문서와 품질 매뉴얼을 모두 제출해주셔야 application review가 진행될 수 있습니다.

MDR 인증가능 코드가 하나라도 부족하면 심사 진행이 어려운가요?

진행이 어렵습니다. 다만, TÜV NORD Poland NB는 지속적으로 심사 코드 확장을 시도하고 있습니다. 추가 코드 획득 시, TÜV NORD Korea 에서도 안내드리겠습니다.
TÜV NORD Poland의 인증가능 품목은 브로셔 마지막장에서 확인하실 수 있습니다.

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F&Q

견적서를 받는데 얼마나 걸릴까요?

- 제출 된 서류에 추가 보완되어야 할 사항이 없을 경우, 통상적으로 견적서 발행까진 3주~4주의 기간이 소요됩니다.
- 견적서에 서명하신 후 3개월 내 심사를 시작할 수 있으며, 인증까지는 통상 9-12개월 정도 소요되고 있습니다.
- TÜV NORD Poland 는 기술문서,품질매뉴얼검토(application review)를 위해 1,000EUR의비용을 청구할 예정입니다.
- 비용 지급이 완료 된 후 정기 conference case를 거쳐 application review가 완료되면 심사일수 산출 후 견적서를 송부할 예정입니다.

견적서를 받는데 왜 비용이 청구되나요?

- 청구되는 비용은 견적서를 위한 비용이 아닌, Application Review 항목의 비용입니다.
- 이는 MDR에 규정되어있는 평가 항목으로, NB별로 청구 시점에 차이가 있을 수 있으나 모든 NB에서 청구되는 항목입니다.
- TÜV NORD Poland의 인증 심사 과정이 단축되며 청구 시점도 앞당겨진 것이며,
- 견적서를 위한 비용이 따로 발생하는 것은 아니라는 점을 말씀드립니다.
- Application Review는 제출된 Application 및 기술문서(TD)와 품질매뉴얼(QM)을 통해 진행되며,적합성 평가절차의 적용 가능성 확인, 제품 분류, Post-market 감사체계, MDR 요구사항에 맞게 업데이트 된 품질 매뉴얼 및 기술문서(임상데이터 및 절차포함) 검토, 심사 인력 가용여부 확인 등이 포함됩니다.

Attachment:

MDR Scope

Notification of a Body in the framework of a technical harmonization directive

From : Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Al. Jerozolimskie 181 C
02-222 Warsaw
Poland

To : **European Commission**
GROWTH Directorate-General
200 Rue de la Loi,
B-1049 Brussels.

Other Member States

Reference : Legislation : Regulation (EU) 2017/745 on medical devices

Body name, address, telephone, fax, email, website :

TUV NORD Polska Sp. z o.o
ul. Mickiewicza 29
40-085 Katowice
Poland
Phone : +48 32 7864646
Fax : +48 32 7864601
Email : biuro@tuv-nord.pl
Website : www.tuv-nord.pl

Body : **NB 2274**

Tasks performed by the Body :

Last approval date : 18/05/2022

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
- A. Active devices			
- 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 a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding MRI
- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) 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	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding products used in ophthalmology
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Including only infusion pumps, devices for dialysis, anaesthesia machines and devices for administration or removal of substances
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding hyperbaric chambers
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) 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	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding active prostheses
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
- B. Non-active devices			
- 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding bone graft substitute for orthopaedic indications, knee, shoulder and hip joint replacement, hyaluronic acid implant for intra-articular use, bone cement
- 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
- 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Including only urological tapes, surgical meshes ligament and tendon prostheses made of multifilament polyester fibers
- 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
	Conformity assessment based on product quality assurance		
- 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding sutures
- 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
- 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) 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 a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
- 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
- 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	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) 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 a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Including only ultrasound gels, medication cups

Horizontal technical competence	Conditions
MDS 1001 Devices incorporating medicinal substances	
MDS 1005 Devices in sterile condition	Including: aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation, filtration
MDS 1006 Reusable surgical instruments	
MDS 1007 Devices incorporating or consisting of nanomaterial	
MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly	

Horizontal technical competence	Conditions
or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body	
MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices	
MDS 1010 Devices with a measuring function	
MDS 1011 Devices in systems or procedure packs	
MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745	Limited to devices emitting electromagnetic radiation for use on the human body according to Annex XVI p. 5
MDS 1013 Class III custom-made implantable devices	
MDT 2001 Devices manufactured using metal processing	
MDT 2002 Devices manufactured using plastic processing	
MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	Excluding processing of glass
MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	Excluding processing of leather
MDT 2006 Devices manufactured using chemical processing	
MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals	
MDT 2008 Devices manufactured in clean rooms and associated controlled environments	
MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin	Excluding processing of animal materials
MDT 2010 Devices manufactured using electronic components including communication devices	
MDT 2011 Devices which require packaging, including labelling	
MDT 2012 Devices which require installation, refurbishment	Limited to electronic devices and medical gas installations

TÜVNORD

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