

TRAINING



TUV NORD Polska Sp. z o.o. invites you to training :

e-learning - Medical Devices Regulation in a nutshell

Training agenda:

- Product qualification as a medical device
- Classification
- Who will cooperate with you?
- Translation and repackaging (importer, distributor)
- How to choose the appropriate certification trail?
- Person responsible for regulatory compliance
- Technical documentation
- Harmonized standards and common specifications (including regeneration)
- Medical Device Coordination Group and MDCG guide lines
- Risk analysis
- Quality management system in MDR
- Clinical evaluation and clinical trials
- Implant card
- Selection of a Notified Body
- European database - EUDAMED
- UDI Codes

Contact:

phone: (32) 786 46 70

e-mail: szkolenia@tuv-nord.pl

www.tuv-nord.pl



E-LEARNING - MEDICAL DEVICES REGULATION IN A NUTSHELL

- Post - market surveillance
- Brexit and regulators update

Training cost:

99 EUR NET per person (+23% VAT) and includes Access to the e-learning is granted after paying the above-mentioned fee. Certificate of training completion can be delivered in electronic version on request. In case of purchasing training for more participants, it is possible to negotiate the price. To order the service and get access to the e-learning training, please send a completed order form to the address: Szkolenia@tuv-nord.pl. We would like to inform you that the standard access time to the training in the e-learning form is 14 days from the date of receiving the access.

Contact:

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Training:		
Unit price:		
Company name:		
Address:		
VAT:		
Item.	Name and surname	Job title
1		
	e-mail:	tel.
2		
	e-mail:	tel.

☐ I consent to processing of my personal data included in this form acc. to Art. 6 sec. 1 point a, b of the Regulation of the European Parliament and of the Council (EU) 2016/679 on the protection of natural persons of 27.04.2016 (Journal of Laws UE L 119, p. 1 hereinafter referred to as "GDPR") by the Administrator, the company: TÜV NORD Polska Sp. z o.o. with headquarters in Katowice, at 40-085 Katowice, ul. Mickiewicza 29, KRS number 118633, for the purpose of providing the training service for the period of its duration and the expiry of the resulting claims. Contact details of the data protection officer: iod@tuv-nord.pl

☐ I have been informed about the right to: access my data, rectify it, delete it, limit processing, transfer it, object to processing and withdraw consent at any time, in accordance with the GDPR by direct contact with the Administrator. I have been informed that the Administrator carries out the processing of my personal data in the scope necessary to provide the training service and that personal data is not transferred to other recipients, is not transferred to a third country or an international organization and is not profiled. I have been informed about the right to lodge a complaint to the President of the Personal Data Protection Office.

I consent to the processing of my personal data (including my e-mail address) for the purpose of receiving commercial information from TÜV NORD Polska within the meaning of the Electronic Communications Act of 12 July 2024 (Journal of Laws 2024 item 1221). I also agree to receive commercial information by e-mail and to use telecommunications terminal equipment for direct marketing purposes*.

☐ YES ☐ NO

☐ Personal data in this form was provided voluntarily and I declare that it's true.

.....
Date and signature of the authorized person

.....
Company stamp

*Please mark

If you wish to receive and electronic invoice, please complete the form below:

Declaration of approval for issuing and sharing invoices in electronic form

1. I hereby declare, that I accept issuing and sending invoices, correction invoices and duplicate invoices in electronic form by TÜV NORD Polska Sp. z o.o., with all legal effects of delivery.
2. Please send VAT invoices issued by TÜV NORD Polska Sp. z o.o. to the following e-mail address:

I declare that I have ready the Regulations for the use of electronic invoices at TNP available on the website <http://efaktura.tuv-nord.pl/> and I accept it.

.....

Date and signature of the authorized person

.....

Company stamp