

QUOTATION REQUEST FORM for system certification

RTF-15-M1-A1
issued: 2026.06.08.
version: 05

Name of the company requesting the quote:			
Registered office:			
Tax number:			
E-mail			
Website			
Manager with power of representation		Contact person / Quality representative	
Name		Name	
Phone		phone number:	
Email address:		Email address:	
Subject of the request for quotation (with relevant specifications), certification of our organization's quality management system			
Certification standard:	☐ MSZ EN ISO 9001:2015		☐ MSZ EN ISO 13485:2016
	Only to be filled in if both standards are selected! ☐ Integrated ☐ Not integrated		
Exclusions:	☐ Non-application:		☐ Design, development (7.3.) ☐ Non-applicable:
Non-application:			
Activities to be certified, scope:	MSZ EN ISO 9001:2015: MSZ EN ISO 13485:2016:		
Products covered by the scope:			
EUDAMED registration number (SRN):			
Activities performed by the organization within the scope:			
Main processes outsourced to subcontractors:			
Number of sites involved in the certification process:			
Was advice sought for the management system? (Yes / No) If yes, which organization?			

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Territorial validity of the certificate and related headcount data			
	Addresses of sites and subcontractors included in the certification (including registered office)	Activities and processes carried out at the site	Number of employees
HQ			
1			
2			
3			
4			
<i>* If you have multiple locations, please also fill out the RTF-15-M1-A2 - quotation request form for multiple locations!</i>			
Work schedule:		Total number of employees involved in the area to be certified:	
Of the employees concerned:			
Number of employees working in one shift:		Number of employees performing similar, simple tasks (e.g., cleaning staff):	
Number of employees working in two shifts:		Number of part-time employees:	
Number of employees working in three shifts:		Number of employees working at external locations:	
Additional relevant information for the certification process			
Planned date of audit:		Do you carry out work at temporary locations?	
Additional information (technical resources, functions, legal obligations)			

Currently valid certificates		
Standard	Name of certification body	Validity period of current certificate

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Other information relevant to the preparation of the offer			
Audit language:	☐ Hungarian ☐ English	Language of documentation:	☐ Hungarian ☐ English
Number of certificates required:		Language of certificates required:	☐ Hungarian ☐ English

Other information and comments related to the quotation:		
Do you manufacture MDR III Class implantable devices, IVDR Class D devices, or devices with a GHTF D risk classification based on IAF ID 13?	☐ Yes	☐ No

If the quotation is accepted, the information provided will form the basis of the contract!

I hereby confirm that the above information is true and accurate:

Date: 20.....month.....day.....

Applicant's name:

Signature of applicant:

Thank you for your cooperation!

Please send the quotation request form to info@nobomed.hu.