1. Information on the manufacturer

Name:				
Single Registration Number (EUDAMED SRN):				
Address of head office:				
Mailing address:				
Tax number:				
E-mail:				
Website:				
Based on 2003/361/EC	☐ micro-enterprise	☐ small business	☐ medium enterprise	☐ not SME
Data for the last closed financial year (To be completed for SMEs)*	**…... year**		**…... year**	
- headcount (pers)	< 10 or < 50 or < 250		< 10 or < 50 or < 250	
- net sales (EUR)	≤ 2 M or ≤ 10M or ≤ 50 M		≤ 2 M or ≤ 10M or ≤ 50 M	
- balance sheet total (EUR)	≤ 2 M or ≤ 10M or ≤ 43 M		≤ 2 M or ≤ 10M or ≤ 43 M	
Related/partner company details (name, address, tax number)				

Manager with representation authority		Contact person	
name:		name:	
phone:		phone:	
e-mail:		e-mail:	

* Data from so-called related and partner enterprises, if any, should also be taken into account.

2. Details of the authorised representative (for non-EU manufacturers)

Name:	
Single Registration Number (EUDAMED SRN):	
Address of head office:	
Mailing address:	
E-mail:	

Manager with representation authority		Contact person	
name:		name:	
phone:		phone:	
e-mail:		e-mail:	

3. Subject of quotation request

Conformity assessment procedure:	**EU 2017/746 (IVDR)** ☐ IVDR Annex IX. Section I. (For Class A sterile devices) ☐ IVDR Annex IX. Section I. and II. ☐ IVDR Annex XI. (For Class A sterile devices)
Name of product(s)/product family(ies):	
Language of the audit:	☐ Hungarian ☐ English
Language of the Quality Management System and Technical File:	☐ Hungarian ☐ English Documentation must be submitted in Hungarian or English only!
Number of certificates requested:	
Language of certificates requested:	

4. Production data

Total number of employees interested under the scope to be certified:	
Number of sites involved in the certification process:	
Main processes subcontracted:	

Address of sites (including headquarters - HQ) involved in certification and names and addresses of critical subcontractors *		Activities and processes on the site	Headcount
HQ			
1.			
2.			
3.			
4.			

* *Additional rows can be added to the list as needed. If you have more than 10 sites/critical suppliers and/or subcontractors, please contact us personally before filling in the form.*

Among the interested employees:

Number of workers	one shift		Number of people performing similar, simple tasks (e.g. cleaning staff):	
	two shifts		Number of part-time workers:	
	hree shifts		Number of people working off-site:	

More relevant information on the certification process

The planned date of the audit:		Do they carry out work on temporary sites:	
More information (technical resources, features, legal obligations)			

5. Currently valid certificates

Standard, legislation	Name of certifying, notified body	Current certificate validity period

6. Other information and comments related to the quotation

7. Product information

Basic information

#	Product name or trade name (as indicated on the label)	Device type (according to basic UDI-DI terminology)	Intended use	Classification		Basic UDI-DI	(EMDN)	Medical device code *	
				Risk class	Classification rule			Product code (IVR)	Special code (IVS, IVP, IVT, IVD)
1.									
2.									
3.									

Additional rows can be added to the list as needed.

Specific information **

#	Product name or trade name (as indicated in basic information)	Device for self-test	Devices used for near-patient laboratory diagnostics	Companion diagnostics	Aseptic processing	Sterile barrier system	Device supplied in sterile state or to be sterilized by the user	Description of sterilisation method	Manufactured using processing of materials of human or animal origin
1.									
2.									
3.									

If the above list has been extended, please do so here as well, and comment on the nature of the products.

* Based on Commission Implementing Regulation (EU) 2017/2185

** Mark the corresponding characteristic with an x!

8. Declarations

Have you already submitted a simultaneous application to another notified body for the same conformity assessment procedure as described in this request for quotation?	☐ yes ☐ no
Have you withdrawn an application to another notified body before it has taken a decision?	☐ yes ☐ no
Has another notified body rejected an application with the same conformity assessment procedure as described in this request for a proposal?	☐ yes ☐ no

If I am submitting the quotation form on behalf of the manufacturer as an EU authorised representative, I acknowledge by my signature that the certification contract for IVDR conformity assessment can only be concluded between the manufacturer and the certification body.

I hereby certify that the above information is true and correct:

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

Name of the applicant: .....

Signature of the applicant: .....

Stamp:

Please send the quotation request form to the following address **"info@nobomed.hu"**

To enable a more efficient review of the quotation form, please attach a short product description (e.g. brochure, technical description, etc.) for each product/product family to be certified.

Attached documents:

1.
2.