1. Information on the manufacturer

Name:	
Single Registration Number (EUDAMED SRN):	
Address of head office:	

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

Name:	
Single Registration Number (EUDAMED SRN):	
Head office:	

3. Subject of application

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)
Products:	Products listed in point 5

4. Production sites

Address of sites (including headquarters - HQ) involved in certification and names and addresses of critical subcontractors / suppliers *		Activities and processes on the site
HQ		
1.		
2.		
3.		
4.		
5.		

5. Product information

Basic information

#	Product name or trade name (as indicated on the label)	Device type (according to basic UDI-DI terminology)	List of production sites (marked according to section 4. e.g. HQ, 1., 4.)	Technical File identifier	Classification		Basic UDI-DI	EMDN	Medical device code *	
					Risk class	Classification rule			Product code (IVR)	Special code (IVS)
1.										
2.										
3.										

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
1.								
2.								
3.								

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

** Mark the corresponding characteristic with an x!

6. Declarations

I hereby apply for the assessment of my quality management system or quality management system and technical documentation in accordance with the conformity assessment procedure set out in point 3 for the product(s) listed in point 5.

I declare that

- - I have not lodged an application with any other notified body concerning the instruments described in this application,
- I have not withdrawn the application to another notified body before the decision of that notified body OR
- I provide all information concerning an application lodged with another notified body which has been withdrawn by that other notified body prior to its decision on conformity assessment, including, where appropriate, information concerning the refusal of the other notified body.

I declare that

- that I fulfil the requirements of Regulation (EU) 2017/746 (IVDR) concerning the establishment, documentation, operation, maintenance, updating and continuous improvement of a quality management system,
- I maintain the proper and effective functioning of the quality management system,
- establish and maintain an up-to-date post-market surveillance system,
- notify the competent authority and NoBoMed Co. Ltd. in accordance with Article 82 of the IVDR:
  - of serious adverse events related to devices placed on the Union market, except for cases clearly documented and quantified in the product information and technical documentation and covered by a trend report under Article 83 of the IVDR,
  - an on-site safety corrective action taken in relation to any device lawfully made available on the Union market, including on-site safety corrective actions taken in a third country in relation to a device lawfully made available on the Union market, where the reason for the on-site safety corrective action is not limited to the third country market, where the device are made available.
- - notify the competent authority and NoBoMed Co. Ltd.. in accordance with Article 83 of the IVDR:
  - of unexpected events other than serious incidents, the frequency or severity of which increases to a statistically significant degree to such an extent that it may have a significant impact on the benefit-risk assessment referred to in points 1 and 8 of Annex I and has or may have an unacceptable risk to the health or safety of patients, users or other persons.

Documentation submitted *

I declare that I submit the following documents with this application:

- Draft EU Declaration of Conformity,
- quality management system documentation,
- technical file(s),
- a documented description of the procedures for compliance with the obligations arising from the quality management system and imposed by the IVDR,
- a description of the procedures to ensure the maintanance of the adequate and efficient operation of the quality management system,
- the documentation concerning the post-market surveillance system and, where applicable, the post-market monitoring plan for performance and the procedures to ensure compliance with the obligations arising from the vigilance provisions of Articles 82 to 87 of the IVDR,
- a description of the procedures to keep the post-market surveillance system and, where applicable, the post-market monitoring plan up to date and a description of the procedures to ensure compliance with the obligations arising from the vigilance provisions of Articles 82 to 87 of the IVDR,
- documentation on the performance assessment plan,
- a description of the procedures to keep the performance assessment plan up to date, taking into account the state of the art.
- for devices in Class C or D, a draft summary of safety and performance (SSP).

- Please list them in section 8. Attachments,

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 upload the completed Application form together with the attachments to the location provided by NoBoMed.

7. Attachments
Draft EU Declaration of Conformity
Quality Management System documentation
Technical File(s)
Documented description of the procedures for compliance with the obligations arising from the quality management system and imposed by the IVDR
Description of the procedures to ensure the maintanance of the adequate and efficient operation of the quality management system
The documentation concerning the post-market surveillance system and, where applicable, the post-market monitoring plan for performance and the procedures to ensure compliance with the obligations arising from the vigilance provisions of Articles 82 to 87 of the IVDR
A description of the procedures to keep the post-market surveillance system and, where applicable, the post-market monitoring plan up to date and a description of the procedures to ensure compliance with the obligations arising from the vigilance provisions of Articles 82 to 87 of the IVDR
Documentation on the performance assessment plan,
A description of the procedures to keep the performance assessment plan up to date, taking into account the state of the art

Additional documents to submit if applying for recertification

In addition to the above, a **summary of the changes and scientific findings** related to the device, including the following, must be submitted when applying for recertification:

(a) all changes to the device as originally approved, including changes not yet notified,

(b) experience gained during post-marketing surveillance,

(c) experience gained in risk management,

(d) experience gained in updating the demonstration of compliance with the general safety and performance requirements laid down in Annex I to the IVDR,

(e) experience gained in performance evaluation reviews, including the results of performance tests and post-market surveillance of performance,

(f) changes in the requirements, the components of the device or the scientific or regulatory environment,

(g) changes to the harmonised standards, uniform specifications or equivalent documents, whether new or in use; and

h) changes in medical, scientific and technical knowledge, such as:

- new treatments,
- changes in testing methods,
- new scientific findings relating to substances and components, including findings relating to their biocompatibility,
- experience gained from studies on similar devices,
- data from registers and registrants,
- experience gained from performance studies on similar devices.

Documents summarising the changes and scientific findings of the device

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

Name of the applicant: .....

Signature of the applicant: .....

Stamp:

To be completed by NoBoMed Co. Ltd.

Review of the application

Aspect of review	Qualification
Are the products in the request and the application the same?	☐ yes ☐ no If not what is the difference:
Is the application complete for the requested conformity procedure with the requirements referred to in the related Annex?	☐ yes ☐ no If not, the justification:
Is the device an in vitro diagnostic medical device and therefore covered by the IVDR?	☐ yes ☐ no If not, the justification:
The risk classification of the device and the applicable classification rule are appropriate?	☐ yes ☐ no If not, the justification:
Is the conformity assessment procedure (pathway) assigned to the device appropriate and applicable to all devices applied for?	☐ yes ☐ no If not, the justification:
Are the devices covered by NoBoMed designation codes?	☐ yes ☐ no
Are the necessary and appropriate resources available?	☐ yes ☐ no
A kérelem tartalmazza? / Does the application include? — the name and registered office of the manufacturer and the address of any additional manufacturing site covered by the quality management system and, if the manufacturer's application is lodged by an authorised representative, the name and registered office of the authorised representative?	☐ yes ☐ no If yes, where?
— all relevant information about the device or group of device covered by the quality management system?	☐ yes ☐ no If yes, where?
— a written declaration that no parallel application has been lodged with any other notified body for the same quality management system relating to the same device, or information on any previous applications for the same quality management system relating to the same device?	☐ yes ☐ no If yes, where?
— the draft EU declaration of conformity in accordance with Article 17 and Annex IV for the device model subject to the conformity assessment procedure?	☐ yes ☐ no If yes, where?
— documentation on the manufacturer's quality management system?	☐ yes ☐ no If yes, where?
— a documented description of the procedures for compliance with the obligations arising from the quality management system and imposed by the IVDR Regulation, and the commitment of the manufacturer concerned to apply these procedures?	☐ yes ☐ no If yes, where?
— a description of the procedures that will ensure the effective and efficient operation of the quality management system and the manufacturer's commitment to apply these procedures?	☐ yes ☐ no If yes, where?

— a description of the procedures that will ensure the effective and efficient operation of the quality management system and the manufacturer's commitment to apply these procedures?	☐ yes ☐ no If yes, where?
— the documentation concerning the manufacturer's post-market surveillance system and, where applicable, the post-market monitoring plan and the procedures to ensure compliance with the obligations arising from the provisions of Articles 82 to 87 on vigilance?	☐ yes ☐ no If yes, where?
— a description of the procedures to keep the post-market surveillance system and, where applicable, the post-market monitoring plan for performance up to date and a description of the procedures to ensure compliance with the obligations arising from the vigilance provisions of Articles 82 to 87 and the manufacturer's commitment to apply these procedures?	☐ yes ☐ no If yes, where?
— documentation on the performance assessment plan?	☐ yes ☐ no If yes, where?
— a description of the procedures to keep the performance assessment plan up to date, taking into account the state of the art?	☐ yes ☐ no If yes, where?
If the customer has submitted a request for recertification of a product, have included a summary of the changes and scientific findings related to the device?	☐ yes ☐ no
Does the summary include? (a) any changes to the originally approved instrument, including changes not yet notified, (b) experience gained during post-market surveillance, (c) experience gained in risk management, (d) experience gained in updating the demonstration of compliance with the general safety and performance requirements set out in Annex I to the IVDR (e) experience gained in performance evaluation reviews, including the results of performance tests and post-market surveillance of performance, (f) changes in the requirements, components of the device or the scientific or regulatory environment, (g) changes in the harmonised standards, uniform specifications or equivalent documents, whether new or in use; and (h) changes in medical, scientific and technical knowledge	☐ yes ☐ no If yes, where?

Proposal for the assessment of the application	
☐ it is proposed to accept the application. ☐ it is proposed to reject the application. Reasons for refusal of the application:	
The review was carried out by	
name:	
position:	Professional Manager
signature:	
date:	
Approved by	
Is the proposal acceptable?	☐ yes ☐ no
Reason if the proposal was not adopted	
name:	
position:	Head of Certification Body
signature:	
date:	