1. Information on the manufacturer

Name:	
Single Registration Number (EUDAMED SRN):	
Address of head office:	
Mailing address:	
Certificate ID:	

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

I declare that there has been a change to report since the last audit of our organisation:

☐ has not occurred.

☐ has occurred as follows:

2. Changes

2.1. Changes of the Quality Management System

Change		Description
Scope	☐ yes	
Company name	☐ yes	
Address of head office	☐ yes	
Number, address of premises (production sites)	☐ yes	
Company form	☐ yes	
Authorised representative	☐ yes	
Organisational structure	☐ yes	
Members of the Management Board	☐ yes	
Quality Manager	☐ yes	
Person Responsible for Regulatory Compliance	☐ yes	
Number of staff under certification scope	☐ yes	
Number of shifts	☐ yes	
Product range	☐ yes	
Applied technologies for manufacturing, technology for packaging etc.	☐ yes	
Significant changes to quality management system processes	☐ yes	
Critical subcontractor(s), supplier(s)	☐ yes	

2.2. Changes of the device		
Change		**Description**
Number of certified devices, versions	☐ yes	
Product name or trade name	☐ yes	
Basic UDI-DI	☐ yes	
Product list	☐ yes	
Approved device design (e.g.: change of technical parameters)	☐ yes	
Approved device type	☐ yes	
Finished and semi-finished product and raw material testing, test methods	☐ yes	
Materials incorporated in or used in the manufacture of the product	☐ yes	
Suppliers	☐ yes	
Packaging	☐ yes	
Medicinal raw material	☐ yes	
Raw material of animal or human origin	☐ yes	
Sterilisation	☐ yes	
Instructions for use, label	☐ yes	
Shelf life	☐ yes	
Softwer	☐ yes	
Indications, contraindications	☐ yes	
Other	☐ yes	

3. Supporting documents, records

Changed quality management system documents	
Technical file (complete)	
Device List	
Company court order (in case of change of details of the manufacturer or authorised representative)	
Other	

Please send the supporting documents, together with the change notification form, to our Office at info@nobomed.hu or via the FTP access requested from our Office.

4. Signature

Manager with representation authority	
name:	
signature:	
date:	

To be filled by NoBoMed Ltd. Co.

ID:	

Evaluation of changes
Does the notified planned change(s) affect the contractual agreement between the manufacturer and NoBoMed Co. Ltd.?
☐ **does not affect** ☐ **affected(s), I initiate the amendment of the contract as Professional Manager.**
Justification:

Assessing the significance of planned changes:
☐ **reassess quality management regulations** ☐ **partially or** ☐ **fully**
☐ **re-evaluate the product documentation:** ☐ **GSPR and/or** ☐ **Risk assessment and/or** ☐ **Technical File and/or** ☐ **Performance assessment and/or** ☐ **Other document:**

The review was made by:			
Name	**Position**	**Signature**	**Date**
	Professional Manager		