ČESKÝ METROLOGICKÝ INSTITUT	**NOTIFIED BODY – NB 1383**

Name:	Czech metrology institute		
Address:	CMI Medical, Hvozdanska 2053/3, 148 00 Praha - Chodov, Czech republic		
Headquarters:	Okruzni 31/772, 638 00 Brno, Czech republic		
CRN / VAT ID:	00177016 / CZ00177016		
Email:	medical@cmi.cz		
Data box:	65msw6w		
Bank account number v CZK:	198139621/0710	**IBAN:**	CZ18 0710 0000 0001 9813 9621
Bank account number v EUR:	34534-198139621/0710	**IBAN:**	CZ88 0710 0345 3401 9813 9621

Non-binding inquiry medical device conformity assessment according to Regulation EU 2017/745 MDR

INSTRUCTIONS

- ✓ All information in this document is **confidential, in accordance with Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data (GDPR)**.
- ✓ A non-binding inquiry **is not the submission of a Medical Device Conformity Assessment Application**. The inquiry results is a **non-binding quotation**, possibly the rejection of the inquiry.
- ✓ The inquiry and attachments must be delivered in **Czech**, **Slovak** or **English**.
- ✓ A requisite attachment of the inquiry is the required **part of the documentation.**
- ✓ More information can be found on the website: **https://www.cmi.cz/mdr**
- ✓ Please tick or select an **option** in the relevant fields, provide a **specific reference** or **identification of the document** and, if applicable, the **chapter/page**.
- ✓ A web link is not sufficient information.
- ✓ Only an electronic version of the documentation in a **searchable format**.
- ✓ The inquiry can be delivered by: **email with electronic signature** or by **company data box.**

Section A: Identification data

IDENTIFICATION OF THE NOTIFIEND BODY'S CONTRACT
(TO BE COMPLETED BY THE NOTIFIED BODY)

CMI inquiry number:		1383-INQ- 2024 /
Contract administrator:		
Contact at CMI:	**Phone:**	
	Email:	

IDENTIFICATION OF CLIENT'S INQUIRY
(TO BE COMPLETED BY CLIENT)

Indicate the number of the inquiry revision:	
Communication language:	Czech
Language of attached documentation:	Czech

INFORMATION ABOUT MANUFACTURER, SENDER OF THE INQUIRY

Manufacturer's name:		
VAT ID number (VAT):		
Registered place of business:		
Single registration num. (SRN):		
Website:		
Statutory representative:	**Name:**	
	Phone:	
	Email:	
Authorised representative: ☐	**Name:**	
	Addess:	
	SRN:	
Invoicing email:		
Bank account number:		
IBAN:		
Administrative contact person (ACP):	**Name:**	
	Phone:	
	Email:	
Technical contact person (TCP, PRRC):	**Name:**	
	Phone:	
	Email:	

NUMBER OF EMPLOYEES OF THE MANUFACTURER, SUBSIDIARIES AND BRANCHES								
Number of shifts:	Number of employees at individual workplaces in the company:							
	Quality control:	Desing and development:	Purchase:	Production:	Warehouse:	Services:	Others:	Total:
								0
Name, address:								
								0
Name, address:								
								0
Name, address:								
								0
Name, address:								
								0
Name, address:								
								0
Name, address:								
								0
Name, address:								
								0
Name, address:								
								0
Name, address:								
Total:	0	0	0	0	0	0	0	0

MANUFACTURER'S QUALITY MANAGEMENT SYSTEM			
Quality system in place:	☐	List of standards:	
Quality system certified:	☐		
Manufacturer use the services of an external consulting company to implement quality management:	☐	Name:	
		Address:	
		Contact:	

Section B: Information related to the inquiry

REQUESTED TYPE OF CONFORMITY ASSESSMENT

◉	A new medical device conformity assessment
○	Approval of change to a medical device
○	Approval of change in QMS / coverage of a range of medical devices
○	Approval of transfer from another notified body to CMI - NB 1383
○	Approval of recertification of medical device (does not apply to MDD-MDR transition)

REQUESTED CONFORMITY ASSESSMENT PROCEDURE

Conformity assessment procedure:	- select -

HISTORY OF APPLICATIONS

Has an application for conformity assessment relating to the device in this inquiry already been submitted to another notified body?	☐	**Provide detailed information:**
Has the application been withdrawn by the manufacturer?	☐	
Has the application been rejected by the notified body?	☐	
Fill in the number of the notified body:	NB	

LIST OF CRITICAL SUPPLIERS				
Name of supplier:				
Address:				
Description of activities carried out:				
Quality system in place:	☐		**List the standards:**	
Quality system certified:	☐			
Name of supplier:				
Address:				
Description of activities carried out:				
Quality system in place:	☐		**List the standards:**	
Quality system certified:	☐			
Name of supplier:				
Address:				
Description of activities carried out:				
Quality system in place:	☐		**List the standards:**	
Quality system certified:	☐			
Name of supplier:				
Address:				
Description of activities carried out:				
Quality system in place:	☐		**List the standards:**	
Quality system certified:	☐			
Name of supplier:				
Address:				
Description of activities carried out:				
Quality system in place:	☐		**List the standards:**	
Quality system certified:	☐			
Name of supplier:				
Address:				
Description of activities carried out:				
Quality system in place:	☐		**List the standards:**	
Quality system certified:	☐			

Section C: Product information

INFORMATION ABOUT MANUFACTURING PROCEDURES AND PRODUCTION

Production in clean rooms:	☐	List the standards:	
Sterilization process validated:	☐	Sterilization performed in-house:	☐

CONTROLLED OR MONITORED ENVIRONMENT

Temperature:	☐	Microbiology:	☐
Humidity:	☐	ESD protection:	☐
Total number of particles:	☐	Radiation protection:	☐
Other (specify):	☐		

PRODUCTION PROCESS TECHNOLOGY

Metal processing (machining…):	☐	Solid connections (soldering, bonding, welding...):	☐
Precise and micro-mechanics:	☐	Plastics and polymer processing:	☐
Ceramics production:	☐	Fiber and textile processing:	☐
Chemical production:	☐	Electronical engineering (circuit boards…):	☐
Biotechnological production:	☐	With knowledge of pharmaceutical production:	☐

INFORMATION ABOUT MEDICAL DEVICES (MD)

1 Name:		Legacy device:	☐
Intended purpose:			
Description, models, variants:			
MDR codes under (EU) 2017/2185:		MD classification:	Im, Is, Ir
MDA/MDN:		The MDR rule applied:	Rule 1
MDS, MDT:		MD used in combination:	A set of devices
Invasive MD:	Non-invasive	Machinery according to 2006/42/ES:	☐
Sterility of MD:	Non-sterile	Carcinogenic and mutagenic substances according 10.4.1 MDR:	☐

2	**Name:**			**Legacy device:**	☐
Intended purpose:					
Description, models, variants:					
MDR codes under (EU) 2017/2185:			**MD classification:**		Im, Is, Ir
MDA/MDN:			**The MDR rule applied:**		Rule 1
MDS, MDT:			**MD used in combination:**		To be used alone
Invasive MD:	Non-invasive		**Machinery according to 2006/42/ES:**		☐
Sterility of MD:	Non-sterile		**Carcinogenic and mutagenic substances according 10.4.1 MDR:**		☐
3	**Name:**			**Legacy device:**	☐
Intended purpose:					
Description, models, variants:					
MDR codes under (EU) 2017/2185:			**MD classification:**		Im, Is, Ir
MDA/MDN:			**The MDR rule applied:**		Rule 1
MDS, MDT:			**MD used in combination:**		To be used alone
Invasive MD:	Non-invasive		**Machinery according to 2006/42/ES:**		☐
Sterility of MD:	Non-sterile		**Carcinogenic and mutagenic substances according 10.4.1 MDR:**		☐
4	**Name:**			**Legacy device:**	☐
Intended purpose:					
Description, models, variants:					
MDR codes under (EU) 2017/2185:			**MD classification:**		Im, Is, Ir
MDA/MDN:			**The MDR rule applied:**		Rule 1
MDS, MDT:			**MD used in combination:**		To be used alone
Invasive MD:	Non-invasive		**Machinery according to 2006/42/ES:**		☐
Sterility of MD:	Non-sterile		**Carcinogenic and mutagenic substances according 10.4.1 MDR:**		☐

5	Name:		Legacy device:	☐
	Intended purpose:			
	Description, models, variants:			
MDR codes under (EU) 2017/2185:		MD classification:		Im, Is, Ir
MDA/MDN:		The MDR rule applied:		Rule 1
MDS, MDT:		MD used in combination:		To be used alone
Invasive MD:	Transiently invasive	Machinery according to 2006/42/ES:		☐
Sterility of MD:	Non-sterile	Carcinogenic and mutagenic substances according 10.4.1 MDR:		☐
6	Name:		Legacy device:	☐
	Intended purpose:			
	Description, models, variants:			
MDR codes under (EU) 2017/2185:		MD classification:		Im, Is, Ir
MDA/MDN:		The MDR rule applied:		Rule 1
MDS, MDT:		MD used in combination:		To be used alone
Invasive MD:	Non-invasive	Machinery according to 2006/42/ES:		☐
Sterility of MD:	Non-sterile	Carcinogenic and mutagenic substances according 10.4.1 MDR:		☐
7	Name:		Legacy device:	☐
	Intended purpose:			
	Description, models, variants:			
MDR codes under (EU) 2017/2185:		MD classification:		Im, Is, Ir
MDA/MDN:		The MDR rule applied:		Rule 1
MDS, MDT:		MD used in combination:		To be used alone
Invasive MD:	Transiently invasive	Machinery according to 2006/42/ES:		☐
Sterility of MD:	Non-sterile	Carcinogenic and mutagenic substances according 10.4.1 MDR:		☐

Section D: Information about attachments of the inquiry

Number of sets of technical documentation for requested medical devices:	

LIST OF REQUIRED ATTACHMENTS TO DEVICES

Suquence number of MD: (Section C)	Documents contain:		EU certificates for MD (if exist):	
	Description of MD:	Instructions for use of MD:	MDD 93/42/EHS:	MDR (EU) 2017/745:
1	☐	☐	☐	☐
2	☐	☐	☐	☐
3	☐	☐	☐	☐
4	☐	☐	☐	☐
5	☐	☐	☐	☐
6	☐	☐	☐	☐
7	☐	☐	☐	☐

LIST OF OTHER ATTACHMENTS OF THE INQUIRY

QMS certificates:		Organizational structures of companies:	Production process maps:
Manufacturer, branches (Section A):	Critical supplies (Section B):		

SPECIFICATION OF OPTIONAL ATTACHMENTS

Identification of document:	Brief description of the content of the document:

Section E: Final information and signatures

ELECTRONIC SIGNATURES OF CLIENT REPRESENTATIVES	
Administrative contact person ACP:	
Statutory representative:	
Signed to date:	

Section F: Administrative data of the notified body

(TO BE COMPLETED BY THE NOTIFIED BODY AFTER THE CONCLUSION OF THE INQUIRY)

Inquiry closed with result:	
Project Leader who prepared the quotation documents:	
The competent authority has submitted a decision on the inquiry: ☐	
Provide detailed information:	
Electronic signature of the Contract administrator of NB:	