mdc	**Application for Surveillance of Legacy Devices according to Regulation (EU) 2017/745 Article 120**	004/01.2024 ID: 11015

After being checked and signed by mdc, this application is a valid **Surveillance Contract** between mdc medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart, Germany (hereinafter mdc) and the following customer:

	Customer number (if available) «Kundennummer»
Exact Name of the Company and legal Entity «Firmenname»	
Single Registration Number (SRN) in EUDAMED (if available)	
Contact Person «Ansprechperson»	
Street «Strasse»	Postal Code, Place «Ort»
Country «Land»	E-mail Address «Email»
Phone «Fon»	Fax «Fax»

Hereby an application is made for the surveillance of legacy devices which are or were certified under Directive 93/42/EEC (MDD), according to Article 120 of Regulation (EU) 2017/745 (MDR). mdc carries out the surveillance with regard to the applied and confirmed scope

This contract is based on the previous contractual agreements including the associated mdc regulations regarding certification according to Directive 93/42/EEC, the **"General Terms of Business"** (396/015), the **"Rules for Certification Procedures According to Regulation (EU) 2017/745"** (5206/004) and the **"«PreislisteEN»"** («PreislisteNummerEN»).

This contract shall be valid from the date of signature by mdc until the deadlines set out in MDR Article 120 (3a), unless otherwise agreed during the quotation process or in the order confirmation. The termination of this contract has to be effected according mdc's General Terms of Business.

Contractual amendments and changes have to be in written form. No additional agreements are existent. The possible invalidity of individual provisions of this contract shall not affect the validity of the remaining provisions. The invalid provision shall be replaced by a valid provision that comes as close as possible to the intended meaning and leads to success.

The manufacturer declares under his sole responsibility that:

- no parallel application for surveillance of the relevant legacy devices has been submitted to any other Notified Body,
- all information on any previous applications to other Notified Bodies under the MDR or Directive 93/42/EEC for the devices covered by the application has been provided in writing to mdc,
- all technical documentations of the devices or device groups on which the application is based continue to be maintained according to the requirements of the MDD and Article 120 MDR.
- all technical documentations of the devices or device groups on which the corresponding application under MDR is based are at a stage of preparation, which will meet the submission schedule agreed with the Notified Body under MDR.
- there are no outstanding deviations from assessments of the technical documentation of the products or product groups which are the basis for this application.
- procedures are in place to ensure that the quality management system remains appropriate and effective, and ***(please select the applicable statement)***
  - ☐ a QMS according to MDR Article 10 (9) is implemented
  - ☐ a QMS according to MDR Article 10 (9) is implemented and a Notified Body has issued the attached certificate for an MDR-compliant QM system.
  - ☐ a QMS according to MDR Article 10 (9) will be implemented by 26 May 2024 at the latest.
- the certification requirements are met on an ongoing basis and all documents and information required under the certification rules are provided,
- staff and representatives of mdc are granted access to all premises during working hours without the need for prior notice and this right of access has been agreed with all subcontractors involved in the development, production, testing and storage and with critical suppliers for their premises.
- for the MDD certificates according to attachment 1 and attachment 2, the conditions of the legal extension according to Article 120 (2) of the MDR are fulfilled.

- the devices listed in attachment 1 and attachment 2 and the manufacturer's processes are in compliance with the conditions for continued placing on the market and putting into service according to MDR Article 120 (3c).

With the application, the manufacturer provides the mdc with the following information:

- a list of the codes (scopes) assigned to the certificates by the previous Notified Body based on the (original) designation,
- the last audit report of the previous Notified Body and, if applicable, deviation reports (if not part of the audit report).

  If the latter contains open deviations:

  - for major deviations: Confirmation of acceptance of the implemented measures by the previous Notified Body.
  - for minor deviations: Confirmation of timely and effective implementation by the manufacturer.

In particular, the following conditions are met:

The MDD certificates covering the listed products were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn by 20 March 2023. They ***(please select the applicable statements)***

☐ were still valid on 20 March 2023

- ☐ a formal application for a conformity assessment procedure according to MDR Annex VII Section 4.3, first subparagraph, for the devices listed in attachment 1 or their successor devices has been submitted to mdc. A signed certification contract according to MDR Annex VII Section 4.3, second subparagraph is in place or will be in place before 26 September 2024.
- ☐ no formal application for a conformity assessment procedure according to MDR Annex VII Section 4.3, first subparagraph for the devices listed in attachment 2 or their successor devices has been submitted to mdc. If the certificates expire after 20 March 2023 and before 26 May 2024, the transition period will end on 26 May 2024 unless an application for a conformity assessment procedure under MDR has been submitted.

☐ expired before 20 March 2023

- ☐ prior to expiry, a formal application for a conformity assessment procedure according to MDR Annex VII Section 4.3, first subparagraph has been submitted to mdc. The application according to MDR includes the devices as specified in attachment 1 or their successor devices and a signed certification contract according to MDR Annex VII Section 4.3, second subparagraph exists.
- ☐ a competent authority has granted an exemption from the applicable conformity assessment procedure according to MDR Article 59 (1) and a formal application for a conformity assessment procedure according to MDR Annex VII Section 4.3, first subparagraph for the devices listed in attachment 1 or their successor devices has been submitted to mdc.
- ☐ a competent authority has requested the manufacturer to carry out an applicable conformity assessment procedure according to MDR Article 97 (1) and a formal application for a conformity assessment procedure according to MDR Annex VII Section 4.3, first subparagraph for the devices listed in attachment 1 or their successor devices has been submitted to mdc

The manufacturer confirms compliance with the post-market surveillance, market surveillance and vigilance requirements as well as economic operator and device registration requirements of the MDR for the devices listed in attachment 1 and attachment 2.

Devices or device categories

The devices or device categories applied for as well as the assessments applied for within the framework of the conformity assessment procedure are listed in the attached "**List of Medical Devices (MDR)**". This has been dated and signed and forms an integral part of this contract.

The products continuously comply with the requirements of the MDD. The devices have not been significantly changed in design or intended purpose since 26 May 2021. The devices do not pose an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of public health protection

It is hereby confirmed to have received and acknowledged the documents referred to on page 1 and to fulfil the obligations contained therein during the validity term of the contract.

Date, stamp

mdc medical device certification GmbH

(legally binding signature manufacturer*)

(date, signature mdc)

(Name in block capitals)

(Name in block capitals)

* Person listed in the commercial register/national register or authorised by means of the power of attorney available on our website.

Attachment 1 - List of products for which a formal MDR application has been submitted to mdc and for which mdc is responsible for appropriate surveillance of the corresponding products in accordance with the applicable directive

Device name and Basic UDI-DI (if available) under MDR application	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1	Class III Class IIb implantable non- WET device Class IIb excluding Class IIb implantable non-WET Class IIa Class I devices placed on the market in sterile condition Class I devices with a measuring function Class I devices that qualify as re-usable surgical instruments Class III implantable custom-made device	N/A or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 2	Class III Class IIb implantable non- WET device Class IIb excluding Class IIb implantable non-WET Class IIa Class I devices placed on the market in sterile condition Class I devices with a measuring function Class I devices that qualify as re-usable surgical instruments Class III implantable custom-made device	N/A or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 3	Class III Class IIb implantable non- WET device Class IIb excluding Class IIb implantable non-WET Class IIa Class I devices placed on the market in sterile condition Class I devices with a measuring function Class I devices that qualify as re-usable surgical instruments Class III implantable custom-made device	N/A or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives

Attachment 2 - List of products for which no formal MDR application has been submitted to mdc and for which mdc GmbH is responsible for appropriate surveillance of the corresponding products in accordance with the applicable directive until May 26, 2024

Device name or Basic UDI-DI (if available)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 **or** **N/A *(to be specified in case there are no devices to be listed in attachment 2)***	Class III Class IIb implantable non- WET device Class IIb excluding Class IIb implantable non-WET Class IIa Class I (sterile) Class I (with measuring function) Class I (re-usable surgical instruments) Class III implantable custom-made device or N/A *(to be specified in case there are no devices to be listed in attachment 2)*	N/A or Identification of the corresponding device under MDD/AIMDD or N/A *(to be specified in case there are no devices to be listed in attachment 2)*	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives or *N/A (to be specified in case there are no devices to be listed in attachment 2)*
Device 2 **or** **N/A *(to be specified in case there are no devices to be listed in attachment 2)***	Class III Class IIb implantable non- WET device Class IIb excluding Class IIb implantable non-WET Class IIa Class I (sterile) Class I (with measuring function) Class I (re-usable surgical instruments) Class III implantable custom-made device or N/A *(to be specified in case there are no devices to be listed in attachment 2)*	N/A or Identification of the corresponding device under MDD/AIMDD or N/A *(to be specified in case there are no devices to be listed in attachment 2)*	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives or *N/A (to be specified in case there are no devices to be listed in attachment 2)*
Device 3 **or** **N/A *(to be specified in case there are no devices to be listed in attachment 2)***	Class III Class IIb implantable non- WET device Class IIb excluding Class IIb implantable non-WET Class IIa Class I (sterile) Class I (with measuring function) Class I (re-usable surgical instruments) Class III implantable custom-made device or N/A *(to be specified in case there are no devices to be listed in attachment 2)*	N/A or Identification of the corresponding device under MDD/AIMDD or N/A *(to be specified in case there are no devices to be listed in attachment 2)*	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives or *N/A (to be specified in case there are no devices to be listed in attachment 2)*