Agreement for continuation of MDD surveillance activities

Regulation (EU) 2023/607

establishing the conditions for the continuation of the relevant surveillance activities pursuant to Article 120(3e) of Regulation (EU) 2017/745[1] in relation to legacy devices for which a certificate in accordance with Directive 93/42/EEC issued by DQS Medizinprodukte GmbH is available.

Upon signature by DQS Medizinprodukte GmbH, this application shall be deemed to be an Agreement for the performance of conformity assessment procedures between

Company: Name und legal form	**Pixmeo SARL**
Address: Street, house number Zip code, city Country	266 rue de Bernex, CH-1233 Bernex, Switzerland
Single Registration number (SRN): *(acc. to Article 31)*	CH-MF-000037624
Contact person: Title, first name, last name	Director, Antoine Rosset
Telephone / Fax:	+41 78 724 30 37, +41 22 757 77 16
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- hereinafter referred to as “CERTIFICATION HOLDER” -,

and

DQS Medizinprodukte GmbH
August-Schanz-Straße 21
60433 Frankfurt am Main
Deutschland

- hereinafter referred to as DQS MED –

The Agreement will be effective on **2024-05-23**:

[1] As extended by the Regulation (EU) 2023/607 of the European Parliament and of the Council dated 15th March 2023.

§ 1 Scope

1. CERTIFICATION HOLDER underwent conformity assessment activities and holds certification issued by DQS MED in accordance with Directive 93/42/EEC that is valid or to be considered to be valid by virtue of paragraph 2 of Article 120 Regulation (EU) 2017/745 covering a device which is placed on the market after date of application of the Regulation (EU) 2017/745 until the date set out in paragraph 3a of Article 120 of this Regulation (hereinafter referred to as "legacy device[2]") that is subject to appropriate surveillance activities in respect of the applicable requirements according to Article 120 (3e) of Regulation (EU) 2017/745 (hereinafter referred to as "appropriate surveillance"), and intends that this appropriate surveillance in respect of that legacy device are continued to be carried out by DQS MED. Appropriate surveillance[3] can include for example documentation review, audits or other kinds of assessments respect of a legacy device (see § 6 (1)) as part of DQS MED's conformity assessment procedure under Regulation (EU) 2017/745. Certification is a valid confirmation in the form of a certification document, in accordance with Directive 93/42/EEC, that conformity assessment activities have been completed successfully and can be supplemented by written confirmations issued by DQS MED [4].

2. The legacy devices that DQS MED issued a certification for and which are subject for continued appropriate surveillance are specified in Appendix 1.

3. Appropriate surveillance may be continued only in respect of a legacy device for as long as it is included in the scope of a certification considered as valid in accordance with Article 120 paragraph 2 or Regulation (EU) 2017/745 and issued by DQS MED covered with the respective designation/notification valid at the time when the certification was issued.

   Certification, which is suspended or temporarily restricted for the relevant legacy device may not be accepted for continued appropriate surveillance in respect of that device.

   Certification, which is withdrawn or otherwise invalidated is not subject to continued appropriate surveillance in respect of that device.

4. DQS MED has to ensure that adequate rights and obligations are agreed with CERTIFICATION HOLDER on a contractual basis to ensure the performance of appropriate surveillance incl. the right to suspend, restrict, withdraw etc. concerned certificates and are subject to this

[2] As per MDCG 2021-25 (Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC (October 2021))

[3] As per MDCG 2022-4 rev. 1 (Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR regarding devices covered by certificates according to the MDD or the AIMDD (December 2022)):

Examples of surveillance activities (non-exhaustive):
- QMS audits
- focused audits (e.g. sterilization, microbiology, supplier etc.)
- unannounced audits
- for cause audits
- change notification assessment, e.g. changes which are considered not to be significant as per Art. 120.3
- Vigilance handling
- appeals
- complaints
- authority notes (e.g. CEFs, classification disputes/decisions)
- certificate actions: withdrawal, suspension, re-instatement, cancellations
- notification to national authorities

[4] According to section 4.3 of MDCG 2020-3 rev. 1 (Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD (May 2023))

agreement; this includes as well auditing rights e.g. on the premises of CERTIFICATE HOLDER and his subcontractors etc.

5. The appropriate surveillance is governed by the terms set out in a certification agreement between CERTIFICATION HOLDER and DQS MED.

6. This Agreement specifies the terms and modalities for the continuance of appropriate surveillance by DQS MED in accordance with the Regulation (EU) 2017/745 and other relevant scheme requirements and ensures the continuity of the activities in accordance with this Regulation and requirements. The appropriate surveillance should be continued in accordance with the applicable requirements of provisions referenced at the end of this Agreement.

§ 2 Agreement conclusion and amendments

The continuance of appropriate surveillance in accordance with this Agreement shall be accomplished in the following steps:

1. (Step 1). The appropriate surveillance process starts with the conclusion of this Agreement, including Appendix 1.

    a. CERTIFICATION HOLDER signs the Agreement. The Agreement shall include Appendix 1. CERTIFICATION HOLDER then forwards the Agreement to DQS MED.

    b. DQS MED verifies and countersigns the Agreement and returns it to CERTIFICATION HOLDER. At this time, any unclarities in the description of appropriate surveillance subject to transfer shall be resolved between the DQS MED and CERTIFICATION HOLDER, and corrections to the Agreement made, as necessary.

2. (Step 2). As soon as DQS MED's activities have progressed sufficiently in order to complete information in Appendix 1, or if it becomes clear that any of this information is no longer correct, the information in Appendix 1 must be supplemented or updated by way of an addendum to this Agreement. The form provided in Appendix 2 should be used for such an addendum, and the signatures may be performed as described in paragraph 1 points a to c.

It is the responsibility of DQS MED to decide whether the continuance of appropriate surveillance is appropriate, what additional assessment activities are needed prior to assuming the responsibility for the appropriate surveillance, and whether they are sufficient to maintain the appropriate surveillance in the way to keep the certification valid in the meaning of § 3 (1).

§ 3 Validity of certification and notified body surveillance activities for the legacy devices subject to transfer of appropriate surveillance

1. CERTIFICATION HOLDER shall comply with the requirements of Article 120 of Regulation (EU) 2017/745 with respect to legacy devices subject to transfer of appropriate surveillance specified in Appendix 1.

2. DQS MED shall not suspend or withdraw the CERTIFICATION HOLDER's certification, in respect of legacy devices subject to continuance of appropriate surveillance specified in Appendix 1, for the only reason as a reaction to the notification that the CERTIFICATION HOLDER is requesting the continuance of appropriate surveillance in respect of a legacy device. The rights of DQS MED to suspend or withdraw certification subject to transfer according to its certification agreement with CERTIFICATION HOLDER remain unaffected.

3. Appropriate surveillance, performed by DQS MED, will be fully continued in respect of the legacy devices specified in Appendix 1.

4. CERTIFICATION HOLDER shall continue to apply the notified body identification number of DQS MED to legacy devices subject to continued appropriate surveillance.

5. CERTIFICATION HOLDER commits to inform DQS MED in writing of the dates when the placing on the market of the legacy devices subject to continued appropriate surveillance under the notified body surveillance activities has been discontinued within 30 days after discontinuation.

§ 4 Assessment prior to continuing appropriate surveillance activities

DQS MED has the full responsibility and authority for the decision, based on information provided by CERTIFICATION HOLDER and publicly available information regarding the extent of its assessment prior to continuing appropriate surveillance. In all cases, DQS MED shall ensure that there is an overview of all required assessment activities and their individual status of completion. Any identified unresolved concerns, findings, non-conformities, surveillance notes, etc. shall be addressed based on their criticality in the scheduling/planning of the consecutive appropriate surveillance activities.

§ 5 Confidentiality and obligation to provide information

In order to allow DQS MED to complete the assessment prior to continuing appropriate surveillance activities according to § 4 and to perform the appropriate surveillance after the TRANSFER DATE (see § 1):

1. CERTIFICATION HOLDER commits to provide on request to the INCOMING NB any relevant information relating to its quality management system. Such a request may include the quality manual and any other document required to allow verification of compliance with requirements layed out in MDR, Article 10 (9) to 10 (13) [5].

[5] Question 11 of Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (March 2023): *Which evidence does the manufacturer have to provide for having put in place a QMS in accordance with the MDR?*
Pursuant to Article 120(3c), point (d), MDR the manufacturer must put in place a QMS in accordance with Article 10(9) MDR no later than 26 May 2024. Manufacturers must draw up the documentation on its QMS, which needs to be part of the application for conformity assessment. Compliance with QMS-related requirements concerning post-market surveillance, market surveillance, vigilance and registration are part of the appropriate surveillance pursuant to Article 120(3e) MDR, while the assessment of the compliance with the MDR of the entire QMS will be done by the notified body as part of its conformity assessment activities.

§ 6 Continued appropriate surveillance

1. Beginning from the date of the countersignature (see § 2 (1) b), DQS MED shall assume full responsibility for the notified body appropriate surveillance activities[6] for the legacy device subject to continued appropriate surveillance, including
    a. any continuing conformity assessment activities
    b. surveillance activities
    c. post-certification monitoring and the assessment of the CERTIFICATION HOLDER's vigilance system with respect to the legacy device manufactured which is under the transferred appropriate surveillance, including NB's involvement in vigilance case assessments
    d. communication with authorities in respect of the legacy device
    e. continued assessment of changes to the device
    f. continued assessment of changes for the related quality management system
    g. issuance of written confirmations to supplement or correct information mentioned in the certification document that covers the legacy device[7] including restriction, suspension and withdrawal of the validity of certification for the legacy device.

2. CERTIFICATION HOLDER shall comply with any requirement to notify the relevant authorities about appropriate surveillance continued by DQS MED in regard to legacy devices.

3. Changes on the device list as per Appendix 1 of this Agreement: based on MDCG 2020-3, rev. 1, section 4.3.2.3, the following changes are considered as "*non-significant change*" towards MDR, Art. 120(3c):

    Change in Specification/Labelling:

    - *change within the currently certified range (more narrow or detailed information), new article inside certified worst case or accepted bracket validations such as:*
        - *o new screw variant within current range of lengths and diameter;*
        - *o new catheter variant, with length and diameter within current range and worst case in sterilisation performance;*
        - *o new stent lengths which are intermediate between the previously certified stent lengths.*

    In respect of this agreement, it means that additional devices might be added under the scope of the MDD certificate. The addition of such additional devices is considered only possible if for the same devices or its substitute device[8] a formal application has been lodged with DQS MED and written agreement for the MDR conformity assessment conducted.

    The responsibility and liability towards the initial certification of the certified range and accepted bracket validations lies with DQS MED.

[6] According to MDCG 2022-4 rev. 1 (Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD (December 2022))
[7] According to section 4.3 of MDCG 2020-3 rev. 1 (Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD (May 2023))
[8] Question 10 of Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (March 2023): "What is the meaning of 'device intended to substitute that device'?"

The responsibility and liability towards the assessment of the appropriateness of the change under Art. 120, and further appropriate surveillance including individual device traceability along the new conditions lies with DQS MED.

§ 7 Settlement and property rights

1. CERTIFICATION HOLDER shall settle, in respect of the legacy device subject to continued appropriate surveillance, all outstanding invoices with DQS MED.

2. All documents provided by DQS MED and all documents (assessment reports, etc.) which were generated by DQS MED for the performance of appropriate surveillance, in respect of the legacy device subject to continued appropriate surveillance, remain property of DQS MED.

§ 8 Miscellaneous

1. (Severability). Should any individual provision of this Agreement or any part of any provision be or become void and/or unenforceable, the validity of the other provisions of the Agreement shall in no way be affected. In such case, the CERTIFICATION HOLDER and DQS MED shall replace, by way of an amendment or change to this Agreement, the void and/or unenforceable provisions with permissible provisions that fulfil the original intent of the void and/or unenforceable provision to the closest possible extent.

2. (Written form). Any amendments or changes to this Agreement shall be made in writing. The form provided in Appendix 2 should be used for such addendum.

3. (Liability). Each party is liable for the part of its contractual and legal duties. Especially DQS MED shall assume full responsibility for contracted surveillance activities with respect to all devices included in the scope of certification subject to continued appropriate surveillance.

   DQS MED recognizes its responsibility for any act or omission. The CERTIFICATION HOLDER commits not to hold DQS MED responsible for these acts or omissions.

4. (Jurisdiction). Unless otherwise agreed, this Agreement shall be governed by, and interpreted in accordance with the substantive laws of the country of DQS MED exclusive of any rules with respect to conflicts of laws.

5. (Disputes). Disputes arising in connection with this Agreement shall be settled by CERTIFICATION HOLDER and DQS MED under the provisions of their certification agreement.

6. (Coming into force) This Agreement comes into force on the date DQS MED has signed this Agreement (also see § 6.1).

The parties confirm that information provided in this Agreement[9] and its Appendix 1 is correct and up-to-date to their best knowledge.

Agreed on behalf of CERTIFICATION HOLDER:

Bernex, May 23rd 2024	**Antoine Rosset**	
Place, date	Name, Signature	

Agreed on behalf of DQS MED:

Frankfurt a. M. 24.09.2024	Ronny Doms	
Place, date	Name, Signature	

Attached:

- ☒ Appendix 1 – Legacy devices subject to transfer of appropriate surveillance (mandatory)
- ☐ Appendix 2 – Addendum form to specify or amend Appendix 1 (optional)

[9] Overview of provisions covered or taken into consideration in this Agreement:

1. Articles 120 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC., as amended by Regulation (EU) 2023/607.
2. MDCG 2020-3 rev.1 (Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD (May 2023))
3. MDCG 2022-4 rev.1 (Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD (December 2022))
4. MDCG 2021-25 (Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC (October 2021))
5. European Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (July 2023)

Appendix 1 – Legacy devices subject to continued appropriate surveillance

Devices covered by this agreement and for which DQS MED (CE 0297) is responsible for the appropriate surveillance of the corresponding devices under the applicable Directive.

MDD Device name or REF	**MDD Certificate Reference(s) of the MDD device**	**Is the device under MDR replaced (substituted) with another device – please identify the corresponding substitute device**	**Maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU 2023/607)[10]**	**Imposed restrictions on the valid and not-suspended certificate or other relevant information**	**Agreed SELL-OFF PERIOD (see § 3 (4))** **If not explicitly specified, the SELL-OFF PERIOD is max. 6 months.**
OsiriX MD	170770516	☒ N/A ☐ Identification of the corresponding substitute device under MDR	☐ YYYY-MM-DD ☐ 2027-12-31 ☒ 2028-12-31		**2028-12-31**

[10] Maximum transition timelines are defined as December 31st 2027 for class III and class IIb implantable devices, and December 31st 2028 for other class IIb, class IIa and class Is, Im and Ir devices.

The parties confirm that information provided in this ADDENDUM to the Application for continuation of MDD surveillance activities and its Appendix 1 is correct and up-to-date to their best knowledge.

Agreed on behalf of CERTIFICATION HOLDER:

Bernex, May 23rd 2024	**Antoine Rosset**	
Place, date	Name, Signature	

Agreed on behalf of DQS MED:

Frankfurt 24.05.2024	Ronny Doms	
Place, date	Name, Signature	