The European Association of Medical devices Notified Bodies

Team-NB Position Paper

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TRANSFER AGREEMENT FOR SURVEILLANCE OF LEGACY DEVICES

specifying the terms of the transfer of the appropriate surveillance activities according to Article 120 (3e) of Regulation (EU) 2017/745[1]

in respect of legacy devices covered by a certificate issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC

The company

<customer name>
<customer address>

- hereinafter referred to as "CERTIFICATION HOLDER" -,

The notified body with the identification number: **<XXXX>**

<new NB name>
<new NB address>

- hereinafter referred to as "INCOMING NB" -,

and

The notified body with the identification number: **<XXXX>**

<previous NB name>
<previous NB address>

- hereinafter referred to as "OUTGOING NB" -

Have concluded the following Agreement under the TRANSFER DATE effective on DD.MM.YYYY:

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

§ 1 Scope

1. CERTIFICATION HOLDER underwent conformity assessment activities and holds certification issued by OUTGOING NB in accordance with Directive 90/385/EEC or 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 in future carried out by the INCOMING NB. Appropriate surveillance[3] can include for example documentation review, audits or other kinds of assessments performed by a notified body in respect of a legacy device (see § 6 (1)) as part of CERTIFICATION HOLDER's previous conformity assessment procedure under Directive 90/385/EEC or Directive 93/42/EEC . Certification is a valid confirmation in the form of a certification document, in accordance with one of these Directives, that conformity assessment activities have been completed successfully and can be supplemented by written confirmations issued by OUTGOING NB [4].

2. The legacy devices that the OUTGOING NB issued a certification for and which are subject to transferred appropriate surveillance to the INCOMING NB (hereinafter referred to as "legacy devices subject to transfer of appropriate surveillance"), and the agreed date on which any review activities by the INCOMING NB in accordance with § 4 are to be completed and from which any surveillance activities by the INCOMING NB are to be carried out and the responsibility for the appropriate surveillance assumed by INCOMING NB (hereinafter referred to as "TRANSFER DATE"), are specified in Appendix 1. The TRANSFER DATE shall not exceed 26 September 2024.

3. Appropriate surveillance may be transferred 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

[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] MDCG 2022-4 Rev.(*enter revision of guidance)* 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

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 MDCG 2020-3 rev 1 section 4.3

paragraph 2 or Regulation (EU) 2017/745 and issued by an OUTGOING NB covered with the respective designation/notification valid at the time when this certification was issued.

Certification, which is suspended or temporarily restricted for the relevant legacy device may not be accepted for transfer of appropriate surveillance in respect of that device, but it is up to the INCOMING NB's decision and subject to the assessment prior to transfer in accordance with § 4. Certification, which is withdrawn or otherwise invalidated prior to TRANSFER DATE is not subject to transfer of appropriate surveillance in respect of that device.

4. The transition of appropriate surveillance in respect of a legacy device from OUTGOING NB to INCOMING NB by way of transfer means that the INCOMING NB, when assuming these activities, takes into account, according to its procedures, the activities of the OUTGOING NB in respect of that device. The INCOMING NB 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 that issued the OUTGOING NB and are subject to this agreement; this includes as well auditing rights e.g. on the premisses of CERTIFICATE HOLDER and his subcontractors etc.

5. The appropriate surveillance subject to transfer performed by OUTGOING NB prior to transfer date is governed by the terms set out in a certification agreement between CERTIFICATION HOLDER and OUTGOING NB. Following the transfer, the OUTGOING NB and the manufacturer shall amend or terminate (whatever is applicable) their certification agreements in respect of legacy devices subject to transfer of appropriate surveillance.

6. This Agreement specifies the terms and modalities for the transfer of appropriate surveillance from an OUTGOING NB to an INCOMING NB in accordance with the Regulation (EU) 2017/745 and other relevant scheme requirements and ensures the continuity of the activities between the OUTGOING NB and the INCOMING NB in accordance with this Regulation and requirements. The appropriate surveillance should be transferred from OUTGOING NB to INCOMING NB in accordance with the applicable requirements of provisions referenced at the end of this Agreement.

§ 2 Agreement conclusion and amendments

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

1. (Step 1)**.** The transfer process starts with the conclusion of this Agreement, including Appendix 1. Specification of TRANSFER DATE in Appendix 1 and the complete Appendix 2 are optional in this step and may be provided in Step 2.

a. CERTIFICATION HOLDER signs the Agreement. The Agreement shall include Appendix 1, and certificates listed in Appendix 1 shall be attached. The Agreement may additionally include Appendix 2. CERTIFICATION HOLDER then forwards the Agreement to INCOMING NB.

b. INCOMING NB 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 INCOMING NB and CERTIFICATION HOLDER, and corrections to the Agreement made, as necessary. The CERTIFICATION HOLDER then forwards the Agreement to the OUTGOING NB.

c. OUTGOING NB verifies and countersigns the Agreement, and forwards it to both CERTIFICATION HOLDER and INCOMING NB.

2. (Step 2). As soon as the INCOMING NB's activities have progressed sufficiently in order to specify the TRANSFER DATE and any other information in Appendices 1 and 2, or if it becomes clear that any of this information is no longer correct, the information in Appendices 1 and 2 must be supplemented or updated by way of an addendum to this Agreement. The form provided in Appendix 3 should be used for such an addendum, and the signatures may be performed as described in paragraph 1 points a to c.

If the involvement of the OUTGOING NB in this Agreement is not practicable[5], only in those cases, the Agreement shall be considered valid with only two signatures. In those cases the obligations of the OUTGOING NB in accordance with this Agreement should be fulfilled by CERTIFICATION HOLDER as far as possible.
In this case, it is the responsibility of the INCOMING NB to decide whether the transition of appropriate surveillance by way of transfer 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).

[5] 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)
Question 14, Answer: *In the third subparagraph of Article 120(3e) MDR, the limitation that requires the notified body that issued the relevant certificate under the MDD/AIMDD to sign the arrangement for the transfer of the appropriate surveillance where practicable takes into account that there might be cases when this notified body could be unable to sign the contract, e.g. termination of business. In any case, it is required to have in place a written agreement between the manufacturer and the MDR notified body to specify the arrangements concerning the appropriate surveillance to be performed by the latter even if the notified body that issued the MDD/AIMDD certificates cannot be involved.*
➔ "Practicable" means that the outgoing NB cannot be reached any longer.

§ 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. OUTGOING NB shall not suspend or withdraw the CERTIFICATION HOLDER's certification, in respect of legacy devices subject to transfer of appropriate surveillance specified in Appendix 1, for the only reason as a reaction to the notification that the CERTIFICATION HOLDER is transferring the appropriate surveillance to the INCOMING NB. The rights of the OUTGOING NB to suspend or withdraw certification subject to transfer according to its certification agreement with CERTIFICATION HOLDER remain unaffected until the date of transfer. Followed by the transfer, contractual agreements shall be amended respectively or terminated (whatever is applicable) (see § 1 (5)).

3. Appropriate surveillance, performed by OUTGOING NB, will be fully transferred in respect of the legacy devices specified in Appendix 1, i.e. equivalent appropriate surveillance will be commenced by the INCOMING NB, on the TRANSFER DATE.

4. CERTIFICATION HOLDER shall continue to apply the notified body identification number of the OUTGOING NB to legacy devices subject to transfer of appropriate surveillance, if not otherwise agreed as per Appendix 2.

5. If agreed as per Appendix 2, the change of notified body identification number from OUTGOING NB to INCOMING NB number shall be documented for devices in the scope of certification the legacy devices subject to transfer of appropriate surveillance on a product-by-product basis during the agreed TRANSITION SELL-OFF PERIOD. The change of notified body number for each device (catalogue number) shall be documented and fixed to a specific serial number or lot number. CERTIFICATION HOLDER commits to document this change for each device (catalogue number) in Appendix 2 and make this information available upon the request of the INCOMING NB.

6. CERTIFICATION HOLDER commits to inform the OUTGOING NB and INCOMING NB in writing of the dates when the placing on the market of the legacy devices subject to transfer of appropriate surveillance under the notified body surveillance activities of the OUTGOING NB has been discontinued within 30 days after discontinuation.

§ 4 Assessment prior to transfer

INCOMING NB has the full responsibility and authority for the decision, based on information provided by CERTIFICATION HOLDER, OUTGOING NB, and publicly available information, regarding the extent of its assessment prior to TRANSFER DATE. In all cases, prior to transferring the appropriate surveillance on the agreed TRANSFER DATE, INCOMING NB 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 by the incoming NB.

§ 5 Confidentiality and obligation to provide information

In order to allow the INCOMING NB to complete the assessment prior to transfer 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 the assessment and certification of a legacy device subject to transfer of appropriate surveillance. Such a request may include valid certificate(s) for the legacy device concerned by the transfer of appropriate surveillance, assessment reports, consultation reports issued by authorities, non-conformities, corrective actions, complaint records, vigilance records and any other relevant records or information of OUTGOING NB or even another previous notified body.

2. CERTIFICATION HOLDER approves that OUTGOING NB may disclose, from the date when this Agreement comes into force (or earlier if agreed in a previous agreement), all information (see items listed in subsection 1), related to the assessment and certification of the legacy devices subject to transfer of appropriate surveillance, to INCOMING NB, to enable any direct communication between OUTGOING NB and INCOMING NB that may be required.

3. CERTIFICATION HOLDER understands that INCOMING NB will contact OUTGOING NB to request information relating to the legacy devices subject to transfer of appropriate surveillance.

4. OUTGOING NB understands and approves that CERTIFICATION HOLDER may disclose to INCOMING NB, from the date when this Agreement comes into force (or earlier if agreed in a previous agreement), all information (see items listed in subsection 1) related to the legacy device subject to transfer of appropriate surveillance.

5. CERTIFICATION HOLDER commits to submit copies of the written confirmation of the transferred appropriate surveillance issued by INCOMING NB to OUTGOING NB without undue delay, at the latest within 30 calendar days of the TRANSFER DATE.

6. CERTIFICATION HOLDER confirms, for each legacy device subject to modification of the labelling by changing the number of the OUTGOING NB to the number of the INCOMING NB, the last serial number or lot number under the notified body appropriate surveillance of the OUTGOING NB, in accordance with Appendix 2. If this information is not yet known on the date when this Agreement comes into force, or changes occur after the date when this Agreement comes into force, CERTIFICATION HOLDER shall submit to OUTGOING NB and INCOMING NB the last serial number or lot number under the notified body oversight of the OUTGOING NB within 30 calendar days of it becoming known or changed. Together with the actual transfer date, this will allow traceability of devices, and responsibilities regarding appropriate surveillance.

§ 6 Continued appropriate surveillance

1. Beginning from the agreed TRANSFER DATE, INCOMING NB shall assume full responsibility for the notified body appropriate surveillance activities[6] for the legacy device subject to transferred 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 transfer of surveillance to INCOMING NB.

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:

[6] General applicable document MDCG 2022-4, 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 (*enter revision of guidance*)

[7] 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 - **Section 4.3**

- *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 **after** the TRANSFER DATE additional devices might be added under the scope of the MDD/AIMDD certificate **without** acknowledgement by the OUTGOING NB initially issued the 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 the MDR Notified Body 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 the OUTGOING NB.

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 the INCOMING NB.

In terms of CExxxx marking, the CERTIFICATION HOLDER and INCOMING NB may decide to agree on the labelling of these specific "legacy devices" indicating the number of the MDR Notified Body, instead of the original MDD/AIMDD certificate issuing OUTGOING NB.

§ 7 Settlement and property rights

1. If not agreed otherwise, CERTIFICATION HOLDER shall settle, in respect of the legacy device subject to transfer of appropriate surveillance, all outstanding invoices with OUTGOING NB and, as applicable, any affiliate of OUTGOING NB supplying notified body certification services under the control of OUTGOING NB.

2. All documents provided by OUTGOING NB and all documents (assessment reports, certificates, etc.) which were generated by OUTGOING NB for the execution of certification, in respect of the legacy device subject to transfer of appropriate surveillance, remain property of the OUTGOING NB.

3. All documents provided by INCOMING NB and all documents (assessment reports, etc.) which were generated by INCOMMING NB for the performance of appropriate surveillance, in respect of the legacy device subject to transfer of appropriate surveillance, remain property of the INCOMING NB.

[8] Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 - Question 10. What is the meaning of "device intended to substitute that device"

§ 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, OUTGOING NB an INCOMING NB 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. This applies especially to any change to an agreed TRANSFER DATE, which shall be agreed-upon in writing, by way of an addendum to this Agreement, between the involved parties prior to the respective previously agreed TRANSFER DATE. The form provided in Appendix 3 should be used for such addendum.

3. (Liability). Each party is liable for the part of its contractual and legal duties. Especially INCOMING NB shall assume full responsibility for contracted surveillance activities, incl. the assessment of the CERTIFICATION HOLDER's vigilance system with respect to all devices included in the scope of certification subject to transferred surveillance. However, according to Art. 120 (3e) subparagraph 3 MDR the INCOMMING NB shall not be responsible for conformity assessment activities incl. previous surveillance activities carried out by OUTGOING NB as the notified body that issued the certificate(s).
   Especially OUTGOING NB shall assume full responsibility for the certification subject to transferred surveillance, including all conformity assessment activities incl. previous surveillance activities prior to TRANSFER DATE.
   In particular, the OUTGOING NB recognises its responsibility for any act or omission accomplished prior to TRANSFER DATE. The CERTIFICATION HOLDER commits not to hold the INCOMING NB 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 INCOMING NB exclusive of any rules with respect to conflicts of laws.

5. (Disputes). Disputes arising in connection with this Agreement shall be settled as follows:

   a. Disputes between CERTIFICATION HOLDER and INCOMING NB shall be settled by CERTIFICATION HOLDER and INCOMING NB under the provisions of their certification agreement.

   b. Disputes between CERTIFICATION HOLDER and OUTGOING NB shall be settled by CERTIFICATION HOLDER and OUTGOING NB under the provisions with regard to appeals of their certification agreement.

6. (Coming into force) This Agreement comes into force on the date the last of the three involved parties, INCOMING NB, OUTGOING NB, and CERTIFICATION HOLDER has signed this Agreement (also see § 6.3).

The parties confirm that information provided in this Agreement and its Appendices 1 and 2 is correct and up-to-date to their best knowledge.

Agreed on behalf of CERTIFICATION HOLDER:	Agreed on behalf of INCOMING NB:	Agreed on behalf of OUTGOING NB:
<place, date>	**<place, date>**	**<place, date>**
……	……	……
<name>	**<name>**	**<name>**
<position>	**<position>**	**<position>**

Attached:

- ☒ Appendix 1 – Legacy devices subject to transfer of appropriate surveillance (mandatory)
- ☒ Copies of certificates specified in Appendix 1 (mandatory)
- ☐ Appendix 2 – Transition provisions (optional)
- ☐ Appendix 3 – Addendum form to specify or amend Appendices 1 and 2 (optional)

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

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

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, 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 transfer of appropriate surveillance

Devices covered by this agreement and for which the incoming NBxxxx is responsible for the appropriate surveillance of the corresponding devices under the applicable Directive

MDD/AIMDD Device name or REF	MDD/AIMDD Certificate Reference(s) of the MDD/AIMDD 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)	Imposed restrictions on the valid and not-suspended certificate or other relevant information	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))
Device 1	Certificate # incl. Rev.	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☐ 31 December 2028		
Device 2	Certificate # incl. Rev.	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☐ 31 December 2028		

Appendix 2 – Traceability table - identification number of the OUTGOING NB to the number of the INCOMING NB

Legacy device subject to transfer of appropriate surveillance	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))	Agreed SELL-OFF PERIOD (see § 3 (4)) If not explicitly specified, the SELL-OFF PERIOD is xx months from the TRANSFER DATE.
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified

Optional

Appendix 3 – Addendum form to specify or amend Appendices 1 and 2

ADDENDUM No. <x>

to the

TRANSFER AGREEMENT coming into force on <date>

between

<customer name>
- "CERTIFICATION HOLDER" -,

<new NB name>
- "INCOMING NB" -, and

<previous NB name>
- "OUTGOING NB" -

The parties have agreed to amend the above-mentioned Agreement as follows in accordance with § 2 (2) and/or § 8 (2):

1. The table in Appendix 1 (Legacy devices subject to transfer of appropriate surveillance) is replaced with the following table:

MDD/AIMDD Device name or REF	MDD/AIMDD Certificate Reference(s) of the MDD/AIMDD 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)	Imposed restrictions on the valid and not-suspended certificate or other relevant information	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))
Device 1	Certificate # incl. Rev.	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☐ 31 December 2028		
Device 2	Certificate # incl. Rev.	☒ N/A or	☐ 31 December 2027 ☐ 31 December 2028		

		☐ Identification of the corresponding substitute device under MDR			

2. The table in Appendix 2 (Transition provisions) is replaced with the following table:

Legacy device subject to transfer of appropriate surveillance	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))	Agreed SELL-OFF PERIOD (see § 3 (4)) If not explicitly specified, the SELL-OFF PERIOD is xx months from the TRANSFER DATE.
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified
	☐ Not yet available	☐ Not explicitly specified

The parties confirm that information provided in this Agreement and its Appendices 1 and 2 is correct and up-to-date to their best knowledge.

Agreed on behalf of CERTIFICATION HOLDER:	Agreed on behalf of INCOMING NB:	Agreed on behalf of OUTGOING NB:
<place, date>	**<place, date>**	**<place, date>**
…… **<name>** **<position>**	…… **<name>** **<position>**	…… **<name>** **<position>**

The European Association of Medical devices Notified Bodies

Team-NB Position Paper

Considerations for the documents checklist:

Checklist of minimum documents to be submitted to the INCOMING NBxxxx by manufacturer or OUTGOING NB:

- Certificate(s)
- Detailed list(s) of device(s) covered by the certificate
- List of conditions correlated to the certificate(s)
- Prior audit reports incl. their findings lists – time frame minimum current certification cycle
- Prior TD assessment reports / expert reports – time frame minimum current certification cycle
- Consultation reports by authorities
- List of vigilance cases
- List of open / still pending non-conformities and their grading (minor/major)
- List of ongoing change notifications being assessed
- Pending appeals

Additionally, the outgoing notified body provides the following to the incoming notified body directly:

- Sampling plan(s) of the current cycle
- Open items to be followed-up, surveillance notes
- Audit program of the current cycle