



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 110 (3e) of Regulation (EU) 2017/746¹
in respect of legacy devices covered by a certificate issued in accordance
with Directive 98/79/EC

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 *as specified in Appendix 1/on DD.MM.YYYY:*

¹ As amended by Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024.



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§ 1 Scope

1. CERTIFICATION HOLDER underwent conformity assessment activities and holds certification issued by OUTGOING NB in accordance with Directive 98/79/EC that is valid by virtue of paragraph 2 of Article 110 Regulation (EU) 2017/746 covering a device which is placed on the market after date of application of the Regulation (EU) 2017/746 until the date set out in paragraph 3a of Article 110 of this Regulation (hereinafter referred to as “legacy device²”) that is subject to appropriate surveillance activities in respect of the applicable requirements according to Article 110 (3e) of Regulation (EU) 2017/746 (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 surveillance³ 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 98/79/EC. Certification is a valid confirmation in the form of a certification document, in accordance with Directive 98/79/EC, 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 are hereinafter referred to as “legacy devices subject to transfer of appropriate surveillance” and are specified in Appendix 1.

The agreed date on which any review activities by the INCOMING NB in accordance with § 4 of the TRANSFER AGREEMENT 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 is hereinafter referred to as “TRANSFER DATE” and is specified in Appendix 1. The TRANSFER DATE shall not exceed 26 September 2025.

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 110 paragraph 2 or Regulation (EU) 2017/746 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

² As per MDCG 2022-8 Regulation (EU) 2017-746 - application of IVDR requirements to ‘legacy devices’ and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC (May 2022)

³ MDCG 2022-15 (in the current revision) “Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD”

⁴ According MDCG 2022-6 (in the current revision) “Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR”.



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INCOMING NB's decision and subject to the assessment prior to transfer in accordance with § 4 of this Agreement.

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 appropriate surveillance activities of the OUTGOING NB in respect of that device (see examples in § 6(1) of this Agreement), but may adapt the surveillance activities to its own procedures and requirements acc. Article 110 paragraph 3, subsection 2, e.g. set up a policy on batch releases for class D devices. The INCOMING NB shall ensure that adequate rights and obligations are agreed with CERTIFICATION HOLDER on a contractual basis to ensure the performance of appropriate surveillance including the right to suspend, restrict, withdraw or take any other measure relating to the concerned certificates that are issued by the OUTGOING NB and which are subject to this agreement. This includes as well auditing rights e.g. on the premisses of CERTIFICATE HOLDER and their 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 CERTIFICATION HOLDER shall amend or terminate (as 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) 2017/746 and other relevant scheme requirements as referred to at the end of this Agreement (see Section "Overview of provisions covered or taken into consideration in this Agreement") and ensures the continuity of the appropriate surveillance activities between the OUTGOING NB and the INCOMING NB in accordance with such requirements.

§ 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 Agreement shall be filled in and signed at first by CERTIFICATION HOLDER, then by INCOMING NB. The CERTIFICATION HOLDER forwards the Agreement to the OUTGOING NB. The Agreement shall be signed at last by OUTGOING NB who forwards it to both CERTIFICATION HOLDER and INCOMING NB.

The Parties shall clarify the content of Appendix 1 and, if applicable, of Appendix 2 between each other.



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- (Step 2). In case the exact TRANSFER DATE has not yet been specified, as soon as the INCOMING NB's activities have progressed sufficiently in order to specify the TRANSFER DATE and any other information in Appendix 1 and, if applicable, Appendix 2, or if it becomes clear that any of this information is no longer correct, the information in Appendix 1 and, if applicable, Appendix 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 Step 1.

If the involvement of the OUTGOING NB in this Agreement is not practicable⁵, 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).

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

- CERTIFICATION HOLDER shall comply with the requirements of Article 110 of Regulation (EU) 2017/746 with respect to legacy devices subject to transfer of appropriate surveillance specified in Appendix 1.
- 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 and duties of the OUTGOING NB to suspend or withdraw certification subject to transfer according to its certification agreement with CERTIFICATION HOLDER remain unaffected until the TRANSFER DATE.
- 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.
- CERTIFICATION HOLDER shall continue to apply the notified body identification number of the OUTGOING NB to legacy devices subject to transfer of appropriate surveillance, unless otherwise agreed as per Appendix 2.

⁵ Q14 of the [Q&A practical aspects 2024/1860](#)



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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 i.e., 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 regarding the extent of its assessment prior to TRANSFER DATE, and after this agreement came into force, based on information provided by CERTIFICATION HOLDER, OUTGOING NB, and publicly available information. 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 of this agreement):

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.



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2. CERTIFICATION HOLDER approves that OUTGOING NB may disclose, from the date when this TRANSFER 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. If agreed as per Appendix 2 of this Agreement, the CERTIFICATION HOLDER confirms, for each legacy device subject to modification of the labelling by changing the identification number of the OUTGOING NB to the identification number of the INCOMING NB, the last serial number or lot number under the appropriate surveillance of the OUTGOING NB, in accordance with Appendix 2. If this information is not yet known on the date when this TRANSFER AGREEMENT comes into force, or changes occur after the date when this TRANSFER AGREEMENT comes into force, CERTIFICATION HOLDER shall submit to OUTGOING NB and INCOMING NB the last serial number or lot number under the appropriate surveillance of the OUTGOING NB within 30 calendar days of it becoming known or changed. Together with the transfer date, this will allow traceability of devices.

§ 6 Continued appropriate surveillance

1. Beginning from the agreed TRANSFER DATE, INCOMING NB shall assume full responsibility for the notified body appropriate surveillance activities⁶ for the legacy device subject to transferred appropriate surveillance, including:

⁶ MDCG 2022-15, “Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD” current revision.



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- a. any continuing conformity assessment activities, incl. QMS audits, focused audits (e.g. sterilization, supplier etc.), unannounced audits, for cause audits
 - 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.g. COEN/CEFs, classification disputes/decisions), notification to national authorities
 - e. appeals and complaints handling
 - f. continued assessment of changes to the device, e.g. changes which are considered not to be significant as per Art. 110.3
 - g. continued assessment of changes for the related quality management system
 - h. issuance of written confirmations to supplement or correct information mentioned in the certification document that covers the legacy device⁷
 - i. certificate actions: including restriction, suspension and withdrawal of the validity of certification for the legacy device, as well as re-instatement and cancellations.
2. CERTIFICATION HOLDER shall comply with any requirement to notify the relevant authorities about transfer of surveillance to INCOMING NB.
3. Changes to the certified device(s) including changes on the device list as per Appendix 1 of this Agreement after the TRANSFER DATE are processed in accordance with the contractual agreements between CERTIFICATION HOLDER and INCOMING NB.
- a. In the cases where these changes are considered⁸ as "non-significant change" in the meaning of IVDR, Art. 110(3c) point (b) by the INCOMING NB such as, for example, a limitation in the intended purpose, in respect of this agreement, it means that **after** the TRANSFER DATE additional devices might be added under the scope of the IVDD 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 device⁹ a formal application has been lodged with the IVDR Notified Body before 26 May 2025, and written agreement for the IVDR conformity assessment conducted before 26 September 2025.
 - b. The responsibility of OUTGOING NB for the initial certification remains unaffected.

⁷ MDCG 2022-6 "Guidance significant changes regarding the transitional provision under Article 110(3) of the IVDR" paragraph 4.1 current revision.

⁸ According to MDCG 2022-6

⁹ Q8 of the [Q&A practical aspects 2024/1860](#)



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§ 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 and ongoing 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 INCOMING 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 Term

The TRANSFER AGREEMENT ends automatically in all cases a legacy device no longer complies with the legal and regulatory requirements as specified in Art. 110 IVDR. In such case the appropriate surveillance by INCOMING NB shall not take place any longer and, if applicable, any accompanying Confirmation Letter, shall automatically and to the extent affected hereby cease to be valid. All transferred information and documents may stay with the INCOMING NB for retention purposes.

§ 9 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 and 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.



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3. (Liability). Each party is liable for the part of its contractual and legal duties in accordance with the following provisions.
 - a. INCOMING NB shall assume full responsibility for contracted surveillance activities, including 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. 110 (3) IVDR, the INCOMING NB shall not be responsible for conformity assessment activities including previous surveillance activities carried out by OUTGOING NB as the notified body that issued the certificate(s) before the TRANSFER DATE. The liability does not apply where the OUTGOING NB has intentionally or through gross negligence concealed incomplete or incorrect performance of any of its duties or obligations.
 - b. 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 recognizes 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. (Applicable Law, 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.



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The parties confirm that information provided in this Agreement and its Appendices 1 and, if applicable Appendix 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>

Attached:

- Appendix 1 – Legacy devices subject to transfer of appropriate surveillance (mandatory)
- Copies of certificates specified in Appendix 1, with any written confirmations to supplement or correct information mentioned in such certificate that covers the legacy devices subject to transfer of appropriate surveillance (mandatory)
(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 110 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on medical devices, on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
2. Q&A on practical aspects related to the implementation of the extended transitional period provided for in the IVDR, as amended by Regulation (EU) 2024/1860 of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices (July 2024)
3. MDCG 2022-15, “Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD”.
4. MDCG 2022-6, “Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR”.
5. MDCG 2022-8 Regulation (EU) 2017/746 - application of IVDR requirements to ‘legacy devices’ and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC (May 2022).



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Appendix 1 – Legacy devices subject to transfer of appropriate surveillance *and* **TRANSFER DATE**

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

IVDD Device name or REF	IVDD Certificate Reference(s) of the IVDD device	Is the device under IVDD replaced (substituted) with another device under IVDR – please identify the corresponding substitute device under IVDR application	Maximum Transition timeline as per in Article 110 (3c) of IVDR (as amended by EU 2024/1860)	Imposed restrictions on the valid and not-suspended IVDD certificate or other relevant information	Agreed TRANSFER DATE (§ 1 (2))
Device 1	Certificate # incl. Rev.	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding substitute device under IVDR	<input type="checkbox"/> 31 December 2027		
Device 2	Certificate # incl. Rev.	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding substitute device under IVDR	<input type="checkbox"/> 31 December 2027		

Optional

Note: If there is no change in NB number with the transfer of appropriate surveillance, then this Appendix shall be deleted/struck through or use “not applicable” check box.

Not applicable



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Appendix 2 – Traceability table - identification number of the OUTGOING NB to the number of the INCOMING NB (if applicable)

Legacy device subject to transfer of appropriate surveillance [IVDD Device name or REF. as in Appendix 1]	The last serial number or lot number for which OUTGOING NB is responsible and for which the identification number of the OUTGOING NB is applied (see § 3 (5))	Agreed SELL-OFF PERIOD (see § 3 (5)) If not explicitly specified, the SELL-OFF PERIOD is xx months from the TRANSFER DATE.
	<input type="checkbox"/> Not yet available	<input type="checkbox"/> Not explicitly specified
	<input type="checkbox"/> Not yet available	<input type="checkbox"/> Not explicitly specified
	<input type="checkbox"/> Not yet available	<input type="checkbox"/> Not explicitly specified



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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 § 9 (2):

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

IVDD Device name or REF	IVDD Certificate Reference(s) of the IVDD device	Is the device under IVDD replaced (substituted) with another device under IVDR – please identify the corresponding substitute IVDR device	Maximum Transition timeline as per in Article 110 (3c) of IVDR (as amended by EU 2024/1860)	Imposed restrictions on the valid and not-suspended IVDD certificate or other relevant information	Agreed TRANSFER DATE (§ 1 (2))
Device 1	Certificate # incl. Rev.	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding substitute device under IVDR	<input type="checkbox"/> 31 December 2027		
Device 2	Certificate # incl. Rev.	<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 31 December 2027		



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		or <input type="checkbox"/> Identification of the corresponding substitute device under IVDR			
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2. The table in Appendix 2 (Transition provisions) is replaced with the following table:

Legacy device subject to transfer of appropriate surveillance [IVDD Device name or REF. as in Appendix 1]	The last serial number or lot number for which OUTGOING NB is responsible and for which the identification number of the OUTGOING NB is applied (see § 3 (5))	Agreed SELL-OFF PERIOD (see § 3 (5)) If not explicitly specified, the SELL-OFF PERIOD is xx months from the TRANSFER DATE.
	<input type="checkbox"/> Not yet available	<input type="checkbox"/> Not explicitly specified
	<input type="checkbox"/> Not yet available	<input type="checkbox"/> Not explicitly specified
	<input type="checkbox"/> Not yet available	<input type="checkbox"/> 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:

<place, date>

.....
<name>
<position>

Agreed on behalf of
INCOMING NB:

<place, date>

.....
<name>
<position>

Agreed on behalf of
OUTGOING NB:

<place, date>

.....
<name>
<position>



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Considerations for the documents checklist:

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

- Copies of certificate specified in Appendix 1, with any written confirmations to supplement or correct information mentioned in such certificate that covers the legacy devices subject to transfer of appropriate surveillance
- Detailed list(s) of device(s) covered by the certificate
- List of conditions correlated to the certificate(s)
- Prior audit reports including their findings lists – time frame minimum current certification cycle
- Prior Technical Documentation 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
- For Annex II List A devices, copies of the final QC release testing for the last three batches performed by the Manufacturer and/or the Certificate of Analysis for that batch performed by the Manufacturer and the relevant labelling for verification

Additionally, the OUTGOING NB provides the following to the INCOMING NB directly:

- Sampling plan(s) of the current cycle
- Open items to be followed-up, surveillance notes
- Audit program of the current cycle
- For Annex II List A devices, Notified Body Annex IV section 6 release notices and supporting documentation (e.g Testing laboratory reports) of the last three batches