The European Association of Medical devices Notified Bodies

Team-NB Position Paper

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AGREEMENT RELATED TO THE TRANSFER OF IVDR FORMAL APPLICATION AND OF APPROPRIATE SURVEILLANCE OF LEGACY DEVICES

specifying the terms of the transfer of Article 110 (3e) application(s) with, where applicable, the transfer of the appropriate surveillance activities according to Article 110 (3e) of Regulation (EU) 2017/746[1] in respect of legacy devices covered by a certificate issued in accordance with Directive 98/79/EC

Note: *"Transfer of IVDR formal application" is intended to address the answer to question 7.1 of the "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" and it covers the transfer of the regulatory status of the IVDR application and the transfer of the regulatory status of the formal written agreement.*

The company (legal manufacturer that submitted a IVDR formal application for conformity assessment activities to the OUTGOING NB)

<customer name>
<customer address>

- hereinafter referred to as "**APPLICANT**" ,

The company (legal manufacturer of the legacy devices subject to transfer of appropriate surveillance)

☐ N.A., no appropriate surveillance to be transferred

or

☐ Same as "APPLICANT"

or

<customer name>
<customer address>

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

- hereinafter referred to as "**CERTIFICATION HOLDER**" ,

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

<Incoming NB name>
<Incoming NB address>

- hereinafter referred to as "INCOMING NB" -,

and

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

<Outgoing NB name>
<Outgoing NB address>

- hereinafter referred to as "OUTGOING NB" -

Have concluded the following Agreement under the TRANSFER DATE effective as specified in Appendix 1.

Preamble:
It is necessary to ensure transfer from one notified body to another notified body even after the relevant deadlines without impacting the fulfilment of the conditions set out in Article 110(3c), point (e), IVDR. In such cases, if the APPLICANT or the outgoing NB terminates the existing IVDR written agreement and the APPLICANT simultaneously enters into a new written agreement with another notified body, to which the IVDR formal application is transferred, the conditions set out in Article 110 (3c) point (e) IVDR are considered to be still met and the transitional period continues to apply.
The purpose of this Agreement is to ensure that, after the relevant deadlines according to Art. 110(3c) point (e) IVDR, the APPLICANT/CERTIFICATION HOLDER can benefit from the transitional period for their legacy devices in accordance with Art. 110 IVDR, without prejudice to any subsequent activities of the INCOMING NB that may rend it inapplicable. On signing this agreement, the regulatory status of the IVDR formal application at the TRANSFER DATE is retained. Where applicable (i.e. IVDD certified devices), the appropriate surveillance is also transferred to INCOMING NB.

§ 1 AGREEMENT RELATED TO THE TRANSFER OF THE IVDR FORMAL APPLICATION

§ 1.1 Scope

1. This Agreement specifies the terms and modalities for the transfer of the IVDR formal application from an OUTGOING NB to an INCOMING NB in accordance with the applicable requirements of the IVDR and ensures the continuity of the activities between the OUTGOING NB and the INCOMING NB in accordance with the IVDR. The IVDR formal application should be transferred from OUTGOING NB to INCOMING NB in accordance with the applicable requirements of provisions referenced at the end of this Agreement. The new formal application should be considered as fulfilling the conditions of IVDR Article 110(3c, point e).

2. APPLICANT lodged within the relevant deadline a IVDR formal application and concluded a IVDR written agreement for conformity assessment activities to/with the OUTGOING NB ("existing (original) IVDR formal application") and intends that all of these activities and certification are in future delivered by INCOMING NB. Conformity assessment activities are described in IVDR Annex VII, section 4.5 and are performed by a notified body as part of APPLICANT's selected conformity assessment procedure pursuant Article 48 of the said Regulation.

3. The devices covered by the IVDR formal application and the written agreement (hereby referred to as "devices covered by the IVDR formal application") stipulated between the APPLICANT and the OUTGOING NB are identified in Appendix 1, table 1 of this agreement.

4. The APPLICANTS's IVDR formal application at the OUTGOING NB is transferred to full or in parts to the INCOMING NB on agreed TRANSFER DATE.

5. The WRITTEN AGREEMENT between APPLICANT and OUTGOING NB is terminated only for devices being the subject of the IVDR formal application transfer as stated in Appendix 1, table 1 on agreed TRANSFER DATE.

6. The transfer of the IVDR formal application from OUTGOING NB to INCOMING NB by way of transfer means that, in case the APPLICANT or the OUTGOING NB terminates the existing written agreement and the APPLICANT simultaneously lodges a corresponding IVDR formal application and enters into a new written agreement with INCOMING NB regarding the corresponding devices, the conditions set out in Article 110 (3c) point (e) IVDR are considered to be still met and the transitional period continues to apply, provided that also the other conditions and applicable regulatory requirements are met.

7. The existing (original) IVDR formal application subject to transfer that has been lodged by APPLICANT at the OUTGOING NB is governed by the terms set out in an IVDR written agreement between APPLICANT and OUTGOING NB until the day preceding the TRANSFER DATE. Similarly, the subsequent IVDR formal application that is lodged by APPLICANT at the INCOMING NB is subject to a separate written agreement between APPLICANT and INCOMING NB starting at 00:00 hours (time zone of INCOMING NB) on AGREED TRANSFER DATE.

8. Where performance verification and/or batch release activities form part of the ongoing conformity assessment of a product, the Manufacturer and the outgoing Notified Body hereby undertake to make available, in full and in a timely manner, all relevant information relating to existing plans and results of such activities. The recipient shall be the incoming Notified Body. At the same time, the Manufacturer and the outgoing Notified Body expressly consent to the disclosure of such information to the aforementioned recipient, insofar as this is necessary to ensure continuity of conformity assessment and testing. This Agreement shall constitute a sufficient basis for the aforementioned obligation and consent.

§ 1.2 Validity of the IVDR formal application subject to transfer

1. APPLICANT should not withdraw their existing (original) IVDR formal application nor cancel the written agreement subject to transfer specified in Appendix 1, table 1 with OUTGOING NB prior to TRANSFER DATE, as this may invalidate the transfer of the IVDR formal application.

2. OUTGOING NB shall not refuse the APPLICANT's IVDR formal application subject to transfer specified in Appendix 1, table 1, following the notification that the APPLICANT is transferring to the INCOMING NB, unless, during the conformity assessment activities, the OUTGOING NB finds there is non-compliance with relevant IVDR requirements that lead to a refusal of the APPLICANT's IVDR formal application or to a refusal of the issuance of a IVDR certificate .

3. The IVDR formal application for devices subject to transfer specified in Appendix 1, table 1, will be fully or partially transferred on the TRANSFER DATE, provided that there is no non-compliance with relevant IVDR requirements that might lead to a refusal of the APPLICANT's IVDR formal application or to a refusal of the issuance of a IVDR certificate. In case the APPLICANT's IVDR formal application is about to be rejected but not formally notified to the APPLICANT or the issuance of the certificate is about to be refused but not formally notified to the APPLICANT, INCOMING NB may, according to its own criteria, decide to continue the transfer process.

§ 2 Transfer of the appropriate surveillance activities according to Article 110 (3e) of Regulation (EU) 2017/746

☐ Not applicable

§ 2.1 Scope

1. This Agreement specifies the terms and modalities for the transfer of appropriate surveillance from the OUTGOING NB to the INCOMING NB in accordance with the IVDR 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. CERTIFICATION HOLDER underwent conformity assessment activities and holds certification issued by OUTGOING NB in accordance with Directive 98/79/EC (hereinafter referred to as "IVDD") that is valid by virtue of Article 110 (2) of the Regulation (EU) 2017/746 (hereinafter referred to as "IVDR") covering a device which is placed on the market after date of application of the IVDR until the date set out in Article 110 (3a) of IVDR (hereinafter referred to as "legacy device [2]") 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 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 § 2.3 (1)) of this Agreement as part of CERTIFICATION HOLDER's previous conformity assessment procedure under IVDD. Certification is a valid confirmation in the form of a certification document, in accordance with this Directive, that conformity assessment activities have been completed successfully and can be supplemented by written confirmations issued by OUTGOING NB [4].

3. 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, table 2.

[2] As per MDCG 2022-8 (current revision) 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

[3] MDCG 2022-15 (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 (current revision), Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR".

The agreed date on which any review activities by the INCOMING NB in accordance with § 3 of this 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, table 2.

4. 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 (2) of IVDR 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 § 3 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.

5. 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 § 2.3(1) of this Agreement). 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 including the right to suspend, restrict, withdraw or take any other measure relating to the 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 CERTIFICATION HOLDER and their subcontractors/suppliers.

6. 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 DATE, 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.

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

1. CERTIFICATION HOLDER shall comply with the requirements of IVDR, Art. 110 with respect to legacy devices subject to transfer of appropriate surveillance specified in Appendix 1, table 2.

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, table 2, 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.

3. Appropriate surveillance, performed by OUTGOING NB, will be fully transferred in respect of the legacy devices specified in Appendix 1, table 2, 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 (or previous outgoing NB) to legacy devices subject to transfer of appropriate surveillance, unless otherwise agreed as per Appendix 2.

5. If agreed as per Appendix 2, the change of notified body identification number from OUTGOING NB (or previous 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.

§ 2.3 Continued appropriate surveillance

1. Beginning from the agreed TRANSFER DATE, INCOMING NB shall assume full responsibility for the notified body appropriate surveillance activities[3] for the legacy device subject to transferred appropriate surveillance, including
   a. any continuing conformity assessment activities, incl. QMS audits, focused audits (e.g. sterilization, microbiology, supplier etc.), unannounced audits, for cause audits, verification of manufactured products covered by Annex II List A, in accordance with Directive 98/79/EC release 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.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 device[5]
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 appropriate surveillance to INCOMING NB.

3. Changes to the certified device(s) including changes on the device list as per Appendix 1, table 2, 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 considered[5] 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 device[6] a formal application was lodged with an IVDR Notified Body before 26 May 2025 (or applicable deadline as per Article 110 .2), and written agreement for the IVDR conformity assessment was conducted before 26 September 2025 (or applicable deadline as per Article 110 .2).
   b) The responsibility of OUTGOING NB for the initial certification remains unaffected.

§ 3 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 comes into force, based on information provided by CERTIFICATION HOLDER/APPLICANT, OUTGOING NB, and publicly available information. In all cases, prior to transferring the IVDR formal application and, where applicable, prior

[5] MDCG 2022-6 "Guidance significant changes regarding the transitional provision under Article 110(3) of the IVDR" paragraph 4.1 current revision.
[6] Q14 of the Q&A practical aspects 2024/1860

to transferring the appropriate surveillance on the agreed TRANSFER DATE, INCOMING NB shall ensure that an overview is provided by the CERTIFICATION HOLDER/APPLICANT and/or OUTGOING NB 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 activities by the INCOMING NB.

§ 4 Confidentiality and obligation to provide information

In order to allow the INCOMING NB to complete the assessment prior to transfer according to § 3 of this Agreement:

1. CERTIFICATION HOLDER/APPLICANT commits to provide on request to the INCOMING NB any relevant information relating to the assessment of any device subject to this transfer agreement. Such a request may include outcome of application(s) review, 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/APPLICANT approves that OUTGOING NB may disclose to INCOMING NB, from the date when this TRANSFER AGREEMENT comes into force, all information (see items listed in subsection 1 above) related to the assessment and certification of any device subject to this transfer agreement, to enable any direct communication between OUTGOING NB and INCOMING NB that may be required.

3. CERTIFICATION HOLDER/APPLICANT understands that INCOMING NB will contact OUTGOING NB to request information related to any device subject to this transfer agreement.

4. OUTGOING NB understands and approves that CERTIFICATION HOLDER/APPLICANT may disclose to INCOMING NB, from the date when this Agreement comes into force, all information (see items listed in subsection 1) related to any device subject to this transfer agreement.

   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 (or previous 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.

§ 5 Settlement and property rights

1. If not agreed otherwise, CERTIFICATION HOLDER/APPLICANT shall settle, in respect any device subject to this transfer agreement, 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 IVDR conformity assessment activities and 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 will be generated by INCOMING NB for the execution of IVDR conformity assessment activities and for the performance of appropriate surveillance in respect of the legacy device subject to transfer of appropriate surveillance remain property of the INCOMING NB.

§ 6 Term

The TRANSFER AGREEMENT terminates automatically in all cases where the existing (original) IVDR formal application lodged at outgoing NB and/or the written agreement concluded with outgoing NB does not comply with the legal and regulatory requirements as specified in IVDR, Art. 110. In such cases, conformity assessment activities will cease and a new IVDR formal application would be required to be submitted by the APPLICANT.
The TRANSFER AGREEMENT terminates automatically in all cases where a legacy device no longer complies with the legal and regulatory requirements as specified in IVDR, Art. 110. In such cases 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.

§ 7 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 this Agreement shall in no way be affected. In such cases, the CERTIFICATION HOLDER/APPLICANT, 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.

3. (Liability). Each party is liable for the part of its contractual and legal duties in accordance with the following provisions.

   INCOMING NB shall assume full responsibility for contracted IVDR conformity assessment activities and, where applicable, appropriate surveillance activities for legacy devices, 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 IVDR, Art. 110 (3e), subparagraph 3, 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 IVDD 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.

   OUTGOING NB shall assume full responsibility for the certification subject to transferred surveillance, including all conformity assessment activities and 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. (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/APPLICANT and INCOMING NB shall be settled by CERTIFICATION HOLDER/APPLICANT and INCOMING NB under the provisions of their certification agreement.

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

c. Disputes between INCOMING NB and OUTGOING NB, or disputes between all the parties, CERTIFICATION HOLDER/APPLICANT, INCOMING NB, and OUTGOING NB, shall be governed by, and interpreted in accordance with the substantive laws of country of INCOMING NB exclusive of any roles with respect to conflicts of laws.

6. (Coming into force) This Agreement comes into force on the date the last of the involved parties, INCOMING NB, OUTGOING NB[7], and CERTIFICATION HOLDER and APPLICANT (where different than the certification holder) has signed this Agreement.

7. (Ends) This Agreement ends automatically in all cases where the IVDR application subject to transfer is refused, withdrawn or otherwise invalidated prior to TRANSFER DATE, or the assessment prior to transfer by the INCOMING NB is not completed successfully (e.g., in case of unresolved issues). Under all such circumstances, all transferred information, and documents may remain with the INCOMING NB for archiving purposes.

§ 8 Agreement conclusion and amendments

The transfer(s) of the IVDR formal application and, where applicable, of appropriate surveillance of legacy devices in accordance with this Agreement shall be accomplished in the following steps:

1. (Step 1). This Agreement shall be filled in and signed at first by CERTIFICATION HOLDER and APPLICANT (where different than the certification holder), then by INCOMING NB. The APPLICANT forwards the Agreement to the OUTGOING NB. The Agreement shall be signed at last by OUTGOING NB who forwards it to both CERTIFICATION HOLDER/APPLICANT and INCOMING NB.
   The Parties shall clarify the content of Appendix 1, and, if applicable, of Appendix 2 between each other.

2. (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, in 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 practicable[7], the Agreement shall be considered valid with the signatures of the CERTIFICATION HOLDER/APPLICANT and of the INCOMING NB. In these cases, the obligations of the OUTGOING NB in accordance with this

[7] Where practicable, as per IVDR article 53. Where practicable considering cases where the OUTGOING NB could be unable to sign this transfer agreement, e.g. termination of business.

Agreement should be fulfilled by CERTIFICATION HOLDER/APPLICANT as far as possible. In this case, it is the responsibility of the INCOMING NB to decide whether the transfer of IVDR application and, if applicable, of appropriate surveillance of related legacy devices, is appropriate, what additional assessment activities are needed prior to assuming the responsibility, and whether there are sufficient elements to maintain the appropriate surveillance in the way to keep the certification valid in the meaning of § 2.2 (1) of this Agreement.

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

Agreed on behalf of the **IVDR APPLICANT** **<place, date>** …… **<name>** **<position>**	Agreed on behalf of the **IVDD CERTIFICATION HOLDER** **<place, date>** …… **<name>** **<position>** **OR** ☐ **N.A., same as IVDR APPLICANT** ☐ **N.A., not subject to transfer of appropriate surveillance**
Agreed on behalf of **INCOMING NB:** **<place, date>** …… **<name>** **<position>**	Agreed on behalf of **OUTGOING NB:** **<place, date>** …… **<name>** **<position>**

The European Association of Medical devices Notified Bodies

Team-NB Position Paper

Attached:

☒ Appendix 1 – Devices covered by the IVDR formal application subject to transfer and legacy devices subject to transfer of appropriate surveillance, including transfer date (mandatory)

☒ Copies of confirmation letters (where issued) and 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)

☐ Appendix 2 – Transition provisions (optional)

☐ Appendix 3 – Addendum form to specify or amend Appendices 1 and/or 2 (optional)

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

1. Article 53 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
2. MDCG 2018-8, "Guidance on content of the certificates, voluntary certificate transfers"
3. Articles 110 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU as amended by Regulation (EU) 2024/1860.
4. MDCG 2022-6, "Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR".
5. 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".
6. MDCG 2019-6 Rev.5 Questions and answers: Requirements relating to notified bodies (in particular, sections I.6.3 and IV. 13 with reference to leveraging evidence)
7. European Commission, Q&A on practical aspects related to the implementation of Regulation (EU) 2024/1860 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 2024)
8. 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

Appendix 1

Devices subject to transfer of the IVDR application and legacy devices subject to transfer of appropriate surveillance

Table 1 - Devices covered by this Agreement and for which the IVDR formal application is being transferred to the INCOMING NBxxxx

The APPLICANT and the OUTGOING NB declare that the IVDR formal application has been submitted by the relevant deadline and that the IVDR written agreement has been concluded by the relevant deadline.

Date when the IVDR formal application has been submitted by the APPLICANT to the OUTGOING NB: *DD.MM.YYYY*
Date when the IVDR written agreement has been concluded by the APPLICANT and the OUTGOING NB: *DD.MM.YYYY*

Name or REF to the device covered by the IVDR formal application	**Confirmation of status of conformity assessment activities and, where applicable, confirmation that there are no non-compliances with relevant IVDR requirements that are going to lead to a refusal of the applicant's application or to a refusal of the issuance of a certificate**	**List of assessments/ audits conducted pursuant art. 48 IVDR by the outgoing NB and associated reports references OR issued IVDR certificate reference(s) (Certificate # incl. Rev.)**	**Agreed TRANSFER DATE (§ 1 (2)) OR reference to the IVDR certificate transfer agreement**
IVDR Device name Intended to substitute legacy device: State legacy device name or ☐ Not applicable	☐Conformity assessment activities have not yet been conducted as per Article 48 IVDR for the device. OR ☐ Conformity assessment activities have been conducted as per Article 48 IVDR for the device (provide the relevant assessment reports or findings to the INCOMING NB). AND ☐ There are no non-compliances with relevant IVDR requirements that are going to lead to a refusal of the application or to a refusal of the issuance of a certificate *OR* ☐ There are non-compliances with relevant IVDR requirements that are going to lead to a refusal of the application or to a refusal of the issuance of a certificate. The transfer of IVDR application CANNOT proceed for this device. OR ☐ IVDR certificate(s) already issued covering this device (a separate transfer of IVDR certification must be signed between INCOMING NB, OUTGOING NB and APPLICANT as per Article 53 IVDR).		☐ Transfer date: DD.MM.YYYY OR ☐ IVDR certificate issued and under a dedicated transfer agreement
IVDR Device name	☐Conformity assessment activities have not yet been conducted as per Article 48 IVDR for the device.		☐ Transfer date: DD.MM.YYYY

Intended to substitute legacy device: State legacy device name or ☐ Not applicable	OR ☐ Conformity assessment activities have been conducted as per Article 48 IVDR for the device (provide the relevant assessment reports or findings to the INCOMING NB). AND ☐ There are no non-compliances with relevant IVDR requirements that are going to lead to a refusal of the application or to a refusal of the issuance of a certificate *OR* ☐ There are non-compliances with relevant IVDR requirements that are going to lead to a refusal of the application or to a refusal of the issuance of a certificate. The transfer of IVDR application CANNOT proceed for this device. OR ☐ IVDR certificate(s) already issued covering this device (a separate transfer of IVDR certification must be signed between INCOMING NB, OUTGOING NB and APPLICANT as per Article 53 IVDR).		OR ☐ IVDR certificate issued and under a dedicated transfer agreement

Table 2 - Devices covered by this Agreement and for which the INCOMING NBxxxx will become responsible for the appropriate surveillance under the applicable Directive as of the transfer date

The agreed transfer date for the transfer of appropriate surveillance for a legacy device is the same transfer date identified in table 1 for the corresponding IVDR device or IVDR substitute device.

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	The last serial number or lot number for which the outgoing notified body is responsible (see § 2.2 (5))
Device 1	Certificate # incl. Rev.	☐ N/A or ☐ Identification of the corresponding IVDR substitute device	☐ 31 December 2027		
Device 2	Certificate # incl. Rev.	☐ N/A or ☐ Identification of the corresponding	☐ 31 December 2027		

		IVDR substitute device			

Appendix 2 – Transition provisions

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**

Traceability table: Identification number of the OUTGOING NB to the identification number of the INCOMING NB

The parties have agreed that the NB number will change from XXXX to XXXX upon the transfer of appropriate surveillance.

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 the OUTGOING NB is responsible and for which the identification number of the OUTGOING NB is applied (see § 2.2 (5))**	**Agreed SELL-OFF PERIOD (see § 2.2 (5))** **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/or 2

ADDENDUM No. <x>
to the
TRANSFER AGREEMENT
coming into force on <date>

between

The company (legal manufacturer that submitted a IVDR formal application for conformity assessment activities to the OUTGOING NB)

<customer name>
<customer address>

- hereinafter referred to as "**APPLICANT**" ,

The company (legal manufacturer of the legacy devices subject to transfer of appropriate surveillance)

☐ N.A., no appropriate surveillance to be transferred

or

☐ Same as "APPLICANT"

or

<customer name>
<customer address>

- hereinafter referred to as "**CERTIFICATION HOLDER**" ,

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

<Incoming NB name>
<Incoming NB address>

- hereinafter referred to as "INCOMING NB" -,

and

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

<Outgoing NB name>
<Outgoing NB address>

- hereinafter referred to as "OUTGOING NB" -

The parties have agreed to amend the above-mentioned Agreement as follows in accordance with § 7 (2) and/or § 8 (2):

1. The tables in Appendix 1 (Devices subject to transfer of the IVDR application and legacy devices subject to transfer of appropriate surveillance) are replaced with the following tables:

Table 1 - Devices covered by this Agreement and for which the IVDR formal application is being transferred to the INCOMING NBxxxx

The APPLICANT and the OUTGOING NB declare that the IVDR formal application has been submitted by the relevant deadline and that the IVDR written agreement has been concluded by the relevant deadline.

Date when the IVDR formal application has been submitted by the APPLICANT to the OUTGOING NB: *DD.MM.YYYY*
Date when the IVDR written agreement has been concluded by the APPLICANT and the OUTGOING NB: *DD.MM.YYYY*

Name or REF to the device covered by the IVDR formal application	**Confirmation of status of conformity assessment activities and, where applicable, confirmation that there are no non-compliances with relevant IVDR requirements that are going to lead to a refusal of the applicant's application or to a refusal of the issuance of a certificate**	**List of assessments/ audits conducted pursuant art. 48 IVDR by the outgoing NB and associated reports references OR issued IVDR certificate reference(s) (Certificate # incl. Rev.)**	**Agreed TRANSFER DATE (§ 1 (2)) OR reference to the IVDR certificate transfer agreement**
IVDR Device name	☐Conformity assessment activities have not yet been conducted as per Article 48 IVDR for the device. OR		☐ Transfer date: DD.MM.YYYY OR

Intended to substitute legacy device: State legacy device name or ☐ Not applicable	☐ Conformity assessment activities have been conducted as per Article 48 IVDR for the device (provide the relevant assessment reports or findings to the INCOMING NB). AND ☐ There are no non-compliances with relevant IVDR requirements that are going to lead to a refusal of the application or to a refusal of the issuance of a certificate *OR* ☐ There are non-compliances with relevant IVDR requirements that are going to lead to a refusal of the application or to a refusal of the issuance of a certificate. The transfer of IVDR application CANNOT proceed for this device. OR ☐ IVDR certificate(s) already issued covering this device (a separate transfer of IVDR certification must be signed between INCOMING NB, OUTGOING NB and APPLICANT as per Article 53 IVDR).		☐ IVDR certificate issued and under a dedicated transfer agreement
IVDR Device name Intended to substitute legacy device: State legacy device name or ☐ Not applicable	☐Conformity assessment activities have not yet been conducted as per Article 48 IVDR for the device. OR ☐ Conformity assessment activities have been conducted as per Article 48 IVDR for the device (provide the relevant assessment reports or findings to the INCOMING NB). AND ☐ There are no non-compliances with relevant IVDR requirements that are going to lead to a refusal of the application or to a refusal of the issuance of a certificate *OR* ☐ There are non-compliances with relevant IVDR requirements that are going to lead to a refusal of the application or to a refusal of the issuance of a certificate. The transfer of IVDR application CANNOT proceed for this device. OR ☐ IVDR certificate(s) already issued covering this device (a separate transfer of IVDR certification must be signed between INCOMING NB, OUTGOING NB and APPLICANT as per Article 53 IVDR).		☐ Transfer date: DD.MM.YYYY OR ☐ IVDR certificate issued and under a dedicated transfer agreement

Table 2 - Devices covered by this Agreement and for which the INCOMING NBxxxx will become responsible for the appropriate surveillance under the applicable Directive as of the transfer date

The agreed transfer date for the transfer of appropriate surveillance for a legacy device is the same transfer date identified in table 1 for the corresponding IVDR device or IVDR substitute device.

IVDD Device name or REF	IVDD Certificate Reference(s) of the IVDD device	Is the device under (AI)MDD 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 (AI)MDD certificate or other relevant information	The last serial number or lot number for which the outgoing notified body is responsible (see § 2.2 (5))
Device 1	Certificate # incl. Rev.	☐ N/A or ☐ Identification of the corresponding IVDR substitute device	☐ 31 December 2027		
Device 2	Certificate # incl. Rev.	☐ N/A or ☐ Identification of the corresponding IVDR substitute device	☐ 31 December 2027		

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 the OUTGOING NB is responsible and for which the identification number of the OUTGOING NB is applied (see § 2.2 (5))**	**Agreed SELL-OFF PERIOD (see § 2.2 (5))** **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 Appendix 1, and if applicable Appendix 2, is correct and up-to-date to their best knowledge.

Agreed on behalf of the
IVDR APPLICANT

<place, date>

……

<name>
<position>

Agreed on behalf of the
MDD/AIMDD CERTIFICATION HOLDER

<place, date>

……

<name>
<position>

OR
☐ **N.A., same as IVDR APPLICANT**
☐ **N.A., not subject to transfer of appropriate surveillance**

Agreed on behalf of
INCOMING NB:

<place, date>

……

<name>
<position>

Agreed on behalf of
OUTGOING NB:

<place, date>

……

<name>
<position>

The European Association of Medical devices Notified Bodies

Team-NB Position Paper

Optional information

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

Transfer of the IVDR formal application	• Copies of confirmation letters (if issued) • Audit reports including their findings lists covering all IVDR formal applications being "transferred" (all reports for current certification cycle, including unannounced audit), if applicable • Technical documentation assessment report(s), and/or list of finding(s) from the assessment, if applicable • Consultation reports by authorities • List of open / still pending non-conformities and their grading (minor/major) and related plan of corrections and corrective / preventative actions • Pending appeals • For Class Ds, Performance Verification report (EURLs) and/or batch testing criteria (if already performed/set/ongoing).
Transfer of appropriate surveillance for legacy devices	• 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 incl. their findings lists – time frame at least current certification cycle • IVDD full technical documentation(s) of legacy device(s) and the latest related assessment report issued by OUTGOING NB - time frame minimum current certification cycle • Consultation reports by authorities • List of vigilance cases – time frame at least current certification cycle • List of open / still pending non-conformities and their grading (minor/major) and related plan of corrections and corrective / preventative actions • 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 • Reports on the verification of manufactured products covered by Annex II, List A for which physical verification of manufactured products was conducted (last three batches, if available)

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

Transfer of the IVDR formal application	• Sampling plan(s) of the current cycle, if established • Open items to be followed-up, surveillance notes • Audit program of the current cycle, if established
Transfer of appropriate surveillance for legacy devices	• 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