



Team-NB Position Paper

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TRANSFER AGREEMENT

specifying the terms of voluntary change of notified body under Regulation (EU) 2017/745 or Regulation (EU) 2017/746

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:

§ 1 Scope

1. CERTIFICATION HOLDER undergoes conformity assessment activities and holds valid certification by OUTGOING NB and intends that all or part of these activities and certification are in future delivered by INCOMING NB. Conformity assessment activities include all audits or other kinds of assessments performed by a notified body as part of CERTIFICATION HOLDER's selected conformity assessment procedure under Regulation (EU) 2017/745 or Regulation (EU) 2017/746. Certification is a valid confirmation in the form of a certification

document, in accordance with one of these Regulations, that conformity assessment activities have been completed successfully. Conformity assessment activities and certification are hereinafter both collectively referred to as “certification”.

2. The certification issued by the OUTGOING NB and which is the subject to transfer to the INCOMING NB (hereinafter referred to as “certification subject to transfer”), and the agreed date on which any review activities by the INCOMING NB are to be completed and transferred and certification issued by INCOMING NB (hereinafter referred to as “transferred certification”) is to become effective (hereinafter referred to as “TRANSFER DATE”), are specified in Appendix 1.
3. Only a valid certification issued by OUTGOING NB covered by valid designation/notification of OUTGOING NB may be transferred. Certification, which is suspended, restricted for the relevant part of the scope of certification, withdrawn or otherwise invalidated prior to TRANSFER DATE may not be accepted for transfer, but is subject to INCOMING NB’s decision.
4. The transition of certification 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.
5. The certification subject to transfer performed by OUTGOING NB is governed by the terms set out in a certification agreement between CERTIFICATION HOLDER and OUTGOING NB until the day preceding the TRANSFER DATE. Similarly, the transferred certification performed by INCOMING NB is subject to a separate certification agreement between CERTIFICATION HOLDER and INCOMING NB starting on the TRANSFER DATE. This Agreement governs the transition of certification may constitute an amendment to these certification agreements.
6. This Agreement specifies the terms and modalities for the transfer of certification /change of notified body from an OUTGOING NB to an INCOMING NB in accordance with the applicable regulations and other requirements of the relevant schemes and ensures the continuity of the activities between the OUTGOING NB and the INCOMING NB in accordance with these regulations and requirements. The certification 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 certification 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 certification 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.

§ 3 Validity of certification subject to transfer

1. CERTIFICATION HOLDER should not cancel their existing certification subject to transfer specified in Appendix 1 with OUTGOING NB prior to TRANSFER DATE, as this may invalidate the transfer process.
2. OUTGOING NB shall not suspend or withdraw the CERTIFICATION HOLDER's certification subject to transfer specified in Appendix 1 following the notification that the CERTIFICATION HOLDER is transferring 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 (see § 1 (5)).
3. Certification subject to transfer specified in Appendix 1, issued by OUTGOING NB, will be fully or partially transferred, i.e. equivalent transferred certification issued by the INCOMING NB, on the TRANSFER DATE, provided that:
 - a. in case the full scope of certification is transferred: the certificate issued by OUTGOING NB becomes invalid on the agreed TRANSFER DATE. OUTGOING NB shall then withdraw the certificate on the TRANSFER DATE, or
 - b. in case a partial scope of certification is transferred: the certificate issued by OUTGOING NB is reissued with the scope of certification reduced by removing the transferred partial scope. OUTGOING NB shall then reissue the certificate with the reduced scope with the effective date identical to the TRANSFER DATE.

Certification subject to transfer issued by OUTGOING NB remains valid until 23:59 hours (time zone of INCOMING NB) of the day preceding TRANSFER DATE. Transferred certification issued by INCOMING NB becomes valid at 00:00 hours (time zone of INCOMING NB) on TRANSFER DATE.

4. The agreed duration of transition period (hereinafter referred to as “TRANSITION PERIOD”) represents the agreed amount of time, starting on TRANSFER DATE, granted for updating the labelling, commensurate with the different industrial manufacturing processes of devices and associated artefacts which will require change and warehouse stock which needs to be sold out. The TRANSITION PERIOD agreed for each device in the scope of certification subject to transfer is specified in Appendix 2. If not explicitly specified, the TRANSITION PERIOD is six (6) months from the TRANSFER DATE.

If the warehouse cannot be sold within the TRANSITION PERIOD, an additional period of sale-off period may be agreed until a specified deadline (hereinafter referred to as “SELL-OFF DEADLINE”). The SELL-OFF DEADLINE shall also be specified in Appendix 2. If not explicitly specified, the SELL-OFF DEADLINE is the end of TRANSITION PERIOD, which means that no additional sale-off period is granted.

5. CERTIFICATION HOLDER shall ensure that the notified body identification number of the respective notified body is applied to devices in the scope of certification subject to transfer strictly within the following limitations:
 - a. Devices in the scope of certification subject to transfer which have been manufactured until 23:59 hours (time zone of the INCOMING NB) on the day preceding TRANSFER DATE shall be placed on the market until end of TRANSITION PERIOD or SELL-OFF DEADLINE with the notified body identification number of OUTGOING NB.
 - b. Devices in the scope of certification subject to transfer which have been manufactured during the TRANSITION PERIOD starting at 00:00 hours (time zone of the INCOMING NB) on TRANSFER DATE may be placed on the market until end of TRANSITION PERIOD or SELL-OFF DEADLINE with the notified body identification number of OUTGOING NB or INCOMING NB. It is not permitted to use both notified body identification numbers simultaneously.
 - c. Devices in the scope of certification subject to transfer which have been manufactured after end of TRANSITION PERIOD shall be placed on the market with the notified body identification number of INCOMING NB.
 - d. After end of the TRANSITION PERIOD or SELL-OFF DEADLINE, CERTIFICATION HOLDER shall no longer place on the market any device in the scope of certification subject to transfer that uses the notified body identification number of OUTGOING NB in any labelling (which includes label, manuals and all other information supplied by the manufacturer, including any promotional material), even if these devices were manufactured during the TRANSITION PERIOD or even before the agreed TRANSFER DATE.
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 devices in the scope of certification subject to

transfer labelled with the identification number of OUTGOING NB has been discontinued within 30 days after discontinuation.

7. The change of notified body identification number shall be implemented for devices in the scope of certification subject to transfer on a product-by-product basis during the TRANSITION PERIOD. The change of notified body identification number for each type of device shall be documented and fixed to a specific serial number or lot number and a specific date. CERTIFICATION HOLDER commits to document this change of identification number for each type of device and make this information available upon the request of the INCOMING NB.

§ 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 issuing any transferred certification, INCOMING NB shall ensure that all required assessment activities are successfully completed, and the documentation received with regard to the corresponding certification subject to transfer does not identify any unresolved concerns.

§ 5 Confidentiality and obligation to provide information

In order to allow the INCOMING NB to complete the assessment prior to transfer according to § 4:

1. CERTIFICATION HOLDER commits to provide on request to the INCOMING NB relevant information relating to the certification subject to transfer. Such a request may include valid certificate(s) concerned by the transfer of certification, assessment reports, scientific opinion 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) until the end of TRANSITION PERIOD or SELL-OFF DEADLINE, all information (see items listed in subsection 1), related to the certification subject to transfer, to INCOMING NB in order 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 certification subject to transfer.
4. OUTGOING NB understands and approves that CERTIFICATION HOLDER 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 certification subject to transfer to INCOMING NB.

5. CERTIFICATION HOLDER commits to submit copies of the new certificate(s) belonging to transferred certification issued by INCOMING NB to OUTGOING NB without undue delay, at the latest within 30 calendar days of the TRANSFER DATE.
6. CERTIFICATION HOLDER shall:
 - a. document the change of notified body through an update of the relevant declaration of conformity for all devices references in Appendix 2, making reference to the certificate(s) belonging to transferred certification issued by INCOMING NB with the effective date of the updated declaration being the agreed TRANSFER DATE,
 - b. submit the draft updated declaration of conformity to INCOMING NB prior to the agreed TRANSFER DATE, and
 - c. sign the updated declaration of conformity on the agreed TRANSFER DATE.
7. CERTIFICATION HOLDER confirms, for each device in the scope of certification subject to transfer, the last serial number or lot number manufactured under the certification issued by 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 manufactured under the certification issued by the OUTGOING NB within 30 calendar days of it becoming known or changed. This will allow both notified bodies to demonstrate to relevant authorities any cases where, although the notified body identification number of OUTGOING NB is affixed on devices placed on the market during the allowed transition period, all notified body responsibilities for these devices have already been transferred to INCOMING NB and the notified body identification number of OUTGOING NB is only being used for the respective device in the scope of transferred certification during the agreed TRANSITION PERIOD.

§ 6 Continued certification

1. Beginning from the agreed TRANSFER DATE, INCOMING NB shall assume full responsibility for the transferred certification, including all conformity assessment activities, surveillance activities and post-certification monitoring and the assessment of the CERTIFICATION HOLDER's vigilance system with respect to all devices manufactured and included in the scope of transferred certification.
2. CERTIFICATION HOLDER shall comply with any requirement to notify the relevant authorities about change of the notified body.

§ 7 Settlement and property rights

1. If not agreed otherwise, CERTIFICATION HOLDER shall settle, before the agreed TRANSFER DATE, 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 subject to transfer prior to the agreed TRANSFER DATE remain property of the OUTGOING NB.

§ 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 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 or TRANSITION PERIOD, 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 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 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.
 - c. Disputes between INCOMING NB and OUTGOING NB, or disputes between the three parties, CERTIFICATION HOLDER, 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 three involved parties, INCOMING NB, OUTGOING NB, and CERTIFICATION HOLDER has signed this Agreement. This Agreement will not come into force in case at least one of the three involved parties did not sign the Agreement.

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>

Attached:

- Appendix 1 – Certification subject to transfer (mandatory)
- Copies of certificates specified in Appendix 1 (mandatory)
- Appendix 2 – Transition provisions (optional)

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

1. Article 58 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. (Applies only to the transfer of certification under Regulation (EU) 2017/745).
2. 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. (Applies only to the transfer of certification under Regulation (EU) 2017/746).
3. MDCG 2018-8 Guidance on content of the certificates, voluntary certificate transfers. November 2018.
4. IAF MD 2:2017 Mandatory Document for the Transfer of Accredited Certification of Management Systems. Issue 2, 15 June 2017. (Taken into consideration).

Appendix 1 – Certification subject to transfer

Current and valid OUTGOING NB certificate number and revision (see § 1 (3))	Scheme	Scope, or part thereof, to be transferred - as displayed on the current OUTGOING NB certificate	Imposed restrictions on the valid and not-suspended certificate or other relevant information	Agreed TRANSFER DATE (see § 1 (4))
	Choose an item.	<input type="checkbox"/> Full scope <input type="checkbox"/> Partial scope:		<input type="checkbox"/> Not yet known
	Choose an item.	<input type="checkbox"/> Full scope <input type="checkbox"/> Partial scope:		<input type="checkbox"/> Not yet known
	Choose an item.	<input type="checkbox"/> Full scope <input type="checkbox"/> Partial scope:		<input type="checkbox"/> Not yet known

Appendix 2 – Transition provisions

Device in the scope of certification subject to transfer	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))	Agreed TRANSITION PERIOD (see § 3 (4)) If not explicitly specified, the TRANSITION PERIOD is 6 months from the TRANSFER DATE.	Agreed SELL-OFF DEADLINE (see § 3 (4)) If not explicitly specified, the SELL-OFF DEADLINE is the end of TRANSITION PERIOD.
	<input type="checkbox"/> Not yet available	<input type="checkbox"/> Not explicitly specified	<input type="checkbox"/> Not explicitly specified
	<input type="checkbox"/> Not yet available	<input type="checkbox"/> Not explicitly specified	<input type="checkbox"/> Not explicitly specified
	<input type="checkbox"/> Not yet available	<input type="checkbox"/> Not explicitly specified	<input type="checkbox"/> Not explicitly specified

Note for final document: This part of the template should have a new page count

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 (Certification subject to transfer) is replaced with the following table:

Current and valid OUTGOING NB certificate number and revision (see § 1 (3))	Scheme	Scope, or part thereof, to be transferred - as displayed on the current OUTGOING NB certificate	Imposed restrictions on the valid and not-suspended certificate or other relevant information	Agreed TRANSFER DATE (see § 1 (4))
	Choose an item.	<input type="checkbox"/> Full scope <input type="checkbox"/> Partial scope:		
	Choose an item.	<input type="checkbox"/> Full scope <input type="checkbox"/> Partial scope:		
	Choose an item.	<input type="checkbox"/> Full scope <input type="checkbox"/> Partial scope:		

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

Device in the scope of certification subject to transfer	The last serial number or lot number labelled with the identification number of OUTGOING NB	Agreed TRANSITION PERIOD (see § 3 (4)) If not explicitly specified, the transition period is 6 months.	Agreed SELL-OFF DEADLINE (see § 3 (4)) If not explicitly specified, the SELL-OFF DEADLINE is the end of TRANSITION PERIOD.
	<input type="checkbox"/> Not yet available	<input type="checkbox"/> Not explicitly specified	<input type="checkbox"/> Not explicitly specified
	<input type="checkbox"/> Not yet available	<input type="checkbox"/> Not explicitly specified	<input type="checkbox"/> Not explicitly specified
	<input type="checkbox"/> Not yet available	<input type="checkbox"/> Not explicitly specified	<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>