

**TRANSFER AGREEMENT FOR SURVEILLANCE OF LEGACY DEVICES SPECIFYING THE TERMS  
OF THE TRANSFER OF THE APPROPRIATE SURVEILLANCE ACTIVITIES ACCORDING TO  
ARTICLE 120 (3E) OF REGULATION (EU) 2017/745<sup>1</sup> IN RESPECT OF LEGACY DEVICES COVERED  
BY A CERTIFICATE ISSUED IN ACCORDANCE WITH DIRECTIVE 90/385/EEC OR DIRECTIVE  
93/42/EEC**

Ref. : SK-0729-MDR-2/23

Concluded between:

The Company *Zhivas Ltd*  
with registered place of business located at *36, Dondukov blvd, 1000, Sofia, Bulgaria*  
represented by *Damian Kamburov, Statutory representative*

Hereinafter referred to as "**Certification Holder**",

Notified Body *SGS Belgium NV*  
with registered place of business located at *SGS House, Noorderlaan 87, 2030 Antwerpen, Belgium*  
entered with the Commercial Register *0404.882.750*  
Notified Body under Directive *90/385/CEE – 93/42/CEE* (identification number 1639)

represented by *Geofrey De Visscher* duly authorized for this purpose

Hereinafter referred to as "**OUTGOING NB**",

AND

*3EC International a.s.*,  
and registered place of business located at *Hraničná 18, 821 05 Bratislava, Slovak Republic.*  
Notified Body under Regulation (EU) 2017/745 (identification number 2265),  
entered with the Municipal Court Bratislava III, Section: Sa, item no:4159/B  
represented by *(Katarína Tomin Srdošová)* duly authorized for this purpose,

Hereinafter referred to as "**3EC**",

under the TRANSFER DATE effective on 01.04.2024.

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<sup>1</sup> As amended by Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023

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## 1. Scope

2. **Certification Holder** underwent conformity assessment activities and holds certification issued by **OUTGOING NB** in accordance with Directive 90/385/EEC or Directive 93/42/EEC, that is valid by virtue of paragraph 2 of Article 120 Regulation (EU) 2017/745, covering a device which is placed on the market after date of application of the Regulation (EU) 2017/745 until the date set out in paragraph 3a of Article 120 of this Regulation (hereinafter referred to as "legacy device"<sup>2</sup>) that is subject to appropriate surveillance activities in respect of the applicable requirements according to Article 120 (3e) of Regulation (EU) 2017/745 (hereinafter referred to as "appropriate surveillance"), and intends that this appropriate surveillance in respect of that legacy device are in future carried out by 3EC. Appropriate surveillance<sup>3</sup> can include for example documentation review, audits or other kinds of assessments performed by a notified body in respect of a legacy device (see § 6 (1)) as part of **Certification Holder's** previous conformity assessment procedure under Directive 90/385/EEC or Directive 93/42/EEC. Certification is a valid confirmation in the form of a certification document, in accordance with one of these Directives, that conformity assessment activities have been completed successfully and can be supplemented by written confirmations issued by **OUTGOING NB**<sup>4</sup>.
3. The legacy devices that **OUTGOING NB** issued a certification for and which are subject to transferred appropriate surveillance to 3EC (hereinafter referred to as "legacy devices subject to transfer of appropriate surveillance"), and the agreed date on which any review activities by 3EC in accordance with § 4 are to be completed and from which any surveillance activities by 3EC are to be carried out and the responsibility for the appropriate surveillance assumed by **3EC** (hereinafter referred to as "TRANSFER DATE"), are specified in Appendix 1. The TRANSFER DATE shall not exceed 26 September 2024.
4. Appropriate surveillance may be transferred only in respect of a legacy device as long as it is included in the scope of a certification considered as valid in accordance with Article 120 paragraph 2 of Regulation (EU) 2017/745 and issued by **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 3EC's decision and subject to the assessment prior to transfer in accordance with § 4.

Certification, which is withdrawn or otherwise invalidated prior to TRANSFER DATE is not subject to transfer of appropriate surveillance in respect of that device.

5. The transition of appropriate surveillance in respect of a legacy device from **OUTGOING NB** to **3EC** by way of transfer means that 3EC, when assuming these activities, takes into account, according to its procedures, the activities of **OUTGOING NB** in respect of that device. 3EC has to ensure that adequate rights and obligations are agreed with **Certification Holder** on a contractual basis to ensure the performance of appropriate surveillance incl. the right to suspend, restrict, withdraw etc. concerned certificates that issued **OUTGOING NB** and are subject to this agreement; this includes as well auditing rights e.g. on the premisses of **CERTIFICATE HOLDER** and his subcontractors etc.
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**

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

<sup>3</sup> MDCG 2022-4 Rev. **2** ) Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR regarding devices covered by certificates according to the MDD or the AIMDD

Examples of surveillance activities (non-exhaustive):

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

<sup>4</sup> According MDCG 2020-3 rev 1 section 4.3



**NB.** Following the transfer, **OUTGOING NB** and the manufacturer shall amend or terminate (whatever is applicable) their certification agreements in respect of legacy devices subject to transfer of appropriate surveillance.

7. This Agreement specifies the terms and modalities for the transfer of appropriate surveillance from **SGS Belgium NV as OUTGOING NB** to 3EC in accordance with the Regulation (EU) 2017/745 and other relevant scheme requirements and ensures the continuity of the activities between **OUTGOING NB** and 3EC in accordance with this Regulation and requirements. The appropriate surveillance should be transferred from **OUTGOING NB** to **3EC** in accordance with the applicable requirements of provisions referenced at the end of this Agreement.

## 2. Agreement conclusion and amendments

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

1. (Step 1). The transfer process starts with the conclusion of this Agreement, including Appendix 1. Specification of TRANSFER DATE in Appendix 1 and the complete Appendix 2 are optional in this step and may be provided in Step 2.
  - a. **Certification Holder** signs the Agreement. The Agreement shall include Appendix 1, and certificates listed in Appendix 1 shall be attached. The Agreement may additionally include Appendix 2. **Certification Holder** then forwards the Agreement to **3EC**.
  - b. **3EC** verifies and countersigns the Agreement and returns it to **Certification Holder**. At this time, any unclarity in the description of appropriate surveillance subject to transfer shall be resolved between 3EC and **SGS Belgium NV**, and corrections to the Agreement made, as necessary. The **Certification Holder** then forwards the Agreement to **OUTGOING NB**.
  - c. **OUTGOING NB** verifies and countersigns the Agreement and forwards it to both **Certification Holder** and **3EC**.
2. (Step 2). As soon as 3EC activities have progressed sufficiently in order to specify the TRANSFER DATE and any other information in Appendices 1 and 2, or if it becomes clear that any of this information is no longer correct, the information in Appendices 1 and 2 must be supplemented or updated by way of an addendum to this Agreement. The form provided in Appendix 3 should be used for such an addendum, and the signatures may be performed as described in paragraph 1 points a to c.

If the involvement of **OUTGOING NB** in this Agreement is not practicable<sup>5</sup>, only in those cases, the Agreement shall be considered valid with only two signatures. In those cases, the obligations of **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 3EC 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 Regulation (UE) 2017/745 article 120 paragraph 2.

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<sup>5</sup> Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (March 2023)

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

→ "Practicable" means that the outgoing NB cannot be reached any longer. 2 signatures (by the manufacturer and INCOMING NB) on this transfer agreement cannot supersede a current valid contract between the MDD/AIMDD Notified Body and the manufacturer.



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

1. **Certification Holder** shall comply with the requirements of Article 120 of Regulation (EU) 2017/745 with respect to legacy devices subject to transfer of appropriate surveillance specified in Appendix 1.
2. **OUTGOING NB** shall not suspend or withdraw the **Certification Holder's** certification, in respect of legacy devices subject to transfer of appropriate surveillance specified in Appendix 1, for the only reason as a reaction to the notification that the **Certification Holder** is transferring the appropriate surveillance to 3EC. The rights of **OUTGOING NB** to suspend or withdraw certification subject to transfer according to its certification agreement with **Certification Holder** remain unaffected until the date of transfer. Followed by the transfer, contractual agreements shall be amended respectively terminated (whatever is applicable) (see § 1 (5)).
3. Appropriate surveillance, performed by **OUTGOING NB**, will be fully transferred in respect of the legacy devices specified in Appendix 1, i.e. equivalent appropriate surveillance will be commenced by 3EC, on the TRANSFER DATE.
4. **Certification Holder** shall continue to apply the notified body identification number of **OUTGOING NB** to legacy devices subject to transfer of appropriate surveillance, if not otherwise agreed as per Appendix 2.
5. If agreed as per Appendix 2, the change of notified body identification number from **OUTGOING NB** to 3EC 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 3EC.
6. **Certification Holder** commits to inform **OUTGOING NB** and 3EC 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 **OUTGOING NB** has been discontinued within 30 days after discontinuation.

### 4. Assessment prior to transfer

3EC has the full responsibility and authority for the decision, based on information provided by **Certification Holder**, **OUTGOING NB**, and publicly available information, regarding the extent of its assessment prior to TRANSFER DATE. In all cases, prior to transferring the appropriate surveillance on the agreed TRANSFER DATE, 3EC 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 3EC.

### 5. Confidentiality and obligation to provide information

In order to allow 3EC to complete the assessment prior to transfer according to § 4 and to perform the appropriate surveillance after the TRANSFER DATE (see § 1):

1. **Certification Holder** commits to provide on request to 3EC any relevant information relating to the assessment and certification of a legacy device subject to transfer of appropriate surveillance. Such a request may include valid certificate(s) for the legacy device concerned by the transfer of appropriate surveillance, assessment reports, consultation reports issued by authorities, non-conformities, corrective actions, complaint records, vigilance records and any other relevant records or information of **OUTGOING NB** or even another previous notified body.



2. **Certification Holder** approves that **OUTGOING NB** may disclose, from the date when this Agreement comes into force (or earlier if agreed in a previous agreement), all information (see items listed in subsection 1), related to the assessment and certification of the legacy devices subject to transfer of appropriate surveillance, to **3EC**, to enable any direct communication between **OUTGOING NB** and **3EC** that may be required.
3. **Certification Holder** understands that **3EC** 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 **3EC**, 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 **3EC** to **OUTGOING NB** without undue delay, at the latest within 30 calendar days of the TRANSFER DATE.
6. **Certification Holder** confirms, for each legacy device subject to modification of the labelling by changing the number of **OUTGOING NB** to the number of **3EC**, the last serial number or lot number under the notified body appropriate surveillance of **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 **3EC** the last serial number or lot number under the notified body oversight of **OUTGOING NB** within 30 calendar days of it becoming known or changed. Together with the actual transfer date, this will allow traceability of devices, and responsibilities regarding appropriate surveillance.

## 6. Continued appropriate surveillance

1. Beginning from the agreed TRANSFER DATE, **3EC** shall assume full responsibility for the notified body appropriate surveillance activities<sup>6</sup> for the legacy device subject to transferred appropriate surveillance, including
  - a. any continuing conformity assessment activities
  - b. surveillance activities
  - c. post-certification monitoring and the assessment of the **Certification Holder's** vigilance system with respect to the legacy device manufactured which is under the transferred appropriate surveillance, including NB's involvement in vigilance case assessments
  - d. communication with authorities in respect of the legacy device
  - e. continued assessment of changes to the device
  - f. continued assessment of changes for the related quality management system
  - g. issuance of written confirmations to supplement or correct information mentioned in the certification document that covers the legacy device<sup>7</sup> including restriction, suspension and withdrawal of the validity of certification for the legacy device.
2. **Certification Holder** shall comply with any requirement to notify the relevant authorities about transfer of surveillance to **3EC**.
3. Changes on the device list as per Appendix 1 of this Agreement: based on MDCG 2020-3, rev. 1, section 4.3.2.3, the following changes are considered as "non-significant change" towards MDR, Art. 120(3c):
 

Change in Specification/Labelling:

  - *change within the currently certified range (more narrow or detailed information), new article inside certified worst case or accepted bracket validations such as:*
    - o new screw variant within current range of lengths and diameter;*

<sup>6</sup> General applicable document MDCG 2022-4, Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD

<sup>7</sup> MDCG 2020-3 Rev.1, Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD - **Section 4.3**



- o new catheter variant, with length and diameter within current range and worst case in sterilisation performance;*
- o new stent lengths which are intermediate between the previously certified stent lengths.*

In respect of this agreement, it means that **after** the TRANSFER DATE additional devices might be added under the scope of the MDD/AIMDD certificate **without** acknowledgement by **OUTGOING NB** that initially issued the certificate.

The addition of such additional devices is considered only possible if for the same devices or its substitute device<sup>8</sup> a formal application has been lodged with the MDR Notified Body and written agreement for the MDR conformity assessment concluded.

The responsibility and liability towards the initial certification of the certified range and accepted bracket validations lies with **OUTGOING NB**.

The responsibility and liability towards the assessment of the appropriateness of the change under Art. 120, and further appropriate surveillance including individual device traceability along the new conditions lies with **3EC**.

In terms of Notified Body identification number accompanying the CE marking, the **Certification Holder** and **3EC** may decide to agree on the labelling of these specific "legacy devices" indicating the number of **3EC**, instead of the original MDD/AIMDD certificate issuing **OUTGOING NB**.

## 7. Settlement and property rights

1. If not agreed otherwise, **Certification Holder** shall settle, in respect of the legacy device subject to transfer of appropriate surveillance, all outstanding invoices with **OUTGOING NB** and, as applicable, any affiliate of **OUTGOING NB** supplying notified body certification services under the control of **OUTGOING NB**.
2. All documents provided by **OUTGOING NB** and all documents (assessment reports, certificates, etc.) which were generated by **OUTGOING NB** for the execution of certification, in respect of the legacy device subject to transfer of appropriate surveillance, remain property of **OUTGOING NB**.
3. All documents provided by **3EC** and all documents (assessment reports, etc.) which were generated by **3EC** for the performance of appropriate surveillance, in respect of the legacy device subject to transfer of appropriate surveillance, remain property of **3EC**.

## 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 **3EC** shall replace, by way of an amendment or change to this Agreement, the void and/or unenforceable provisions with permissible provisions that fulfil the original intent of the void and/or unenforceable provision to the closest possible extent.
2. (Written form). Any amendments or changes to this Agreement shall be made in writing. This applies especially to any change to an agreed TRANSFER DATE, which shall be agreed-upon in writing, by way of an addendum to this Agreement, between the involved parties prior to the respective previously agreed TRANSFER DATE. The form provided in Appendix 3 should be used for such addendum.
3. (Liability). Each party is liable for the part of its contractual and legal duties. Especially **3EC** shall assume full responsibility for contracted surveillance activities, incl. the assessment of the **Certification Holder's** vigilance system with respect to all devices included in the scope of certification subject to transferred surveillance. However, according to Art. 120 (3e) subparagraph 3 MDR **3EC** shall not be responsible for conformity assessment activities incl. previous surveillance activities carried out by **OUTGOING NB** as the notified body that issued the certificate(s).

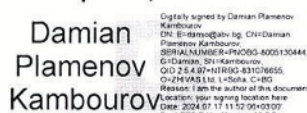


<sup>8</sup> Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 - Question 10. What is the meaning of "device intended to substitute that device"

Especially **OUTGOING NB** shall assume full responsibility for the certification subject to transferred surveillance, including all conformity assessment activities incl. previous surveillance activities prior to TRANSFER DATE.

In particular, **OUTGOING NB** recognises its responsibility for any act or omission accomplished prior to TRANSFER DATE. The **Certification Holder** commits not to hold **3EC** responsible for these acts or omissions.

4. (Jurisdiction). Unless otherwise agreed, this Agreement shall be governed by, and interpreted in accordance with the substantive laws of the country of **3EC** 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 **3EC** shall be settled by **Certification Holder** and **3EC** 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, **3EC**, **OUTGOING NB**, and **Certification Holder** has signed this Agreement (also see § 6.3).

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

Agreed on behalf of <b>Certification Holder :</b>	Agreed on behalf of <b>3EC :</b>	Agreed on behalf of <b>OUTGOING NB :</b>
17-Jul-24; Sofia, Bulgaria <place, date>	18-Jul-2024 <Bratislava, Slovakia, date.....>	11-Jul-24 <place, date>
 Damian Plamenov Kamburov ..... <name> Damian <position> Kamburov Managing director	 ....., PhD. > .....>	 ..... <name> Geoffrey De <position> Visscher Head Of Notified Body 1639

Attached:

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

**3EC International a.s.** ①  
Hraničná 18, 821 05 Bratislava  
Slovenská republika  
IČO: 36 789 003  
IČ DPH: SK2022390073



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

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

Considerations for the documents checklist:

**Checklist of minimum documents to be submitted to 3EC 2265 by manufacturer or OUTGOING NB:**

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

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

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

## Appendix 1 – Legacy devices subject to transfer of appropriate surveillance

Devices covered by this agreement and for which 3EC 2265 is responsible for the appropriate surveillance of the corresponding devices under the applicable Directive

MDD/AIMDD Device name or REF	MDD/AIMDD Certificate Reference(s) of the MDD/AIMDD device	Is the device under MDR replaced (substituted) with another device – please identify the corresponding substitute device	Maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU 2023/607)	Imposed restrictions on the valid and not-suspended certificate or other relevant information	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5))
Disinfectant, Trade name: ZHIVAHEX MD, Alternative trade name: Alkadez spray MD (North Macedonia), Zhivahex spray MD (Pakistan), Batihex spray MD (Czech Republic) Variants: 200 ml, 750 ml, 1L, 3L, 5L and 10L	MDD Certificate BG19/871876;	N/A	<input checked="" type="checkbox"/> 31 December 2028	N/A	LOT no.: 413
Disinfectant, Trade name: Glutasept S Variants: 1L and 5L	MDD Certificate BG19/871876;	N/A	<input checked="" type="checkbox"/> 31 December 2028	N/A	LOT no.: 041
Disinfectant, Trade name: Enzydip-3 AM, Alternative Trade Name: Alkadez Enzy (North Macedonia) Variants: 1L and 5L	MDD Certificate BG19/871876;	N/A	<input checked="" type="checkbox"/> 31 December 2028	N/A	LOT no.: 078
Disinfectant, Trade name: Oxisept, Alternative Trade Name: Variants: 1kg, 3 kg, 5 kg	MDD Certificate BG19/871876;	N/A	<input checked="" type="checkbox"/> 31 December 2028	N/A	LOT no.: 200
Disinfectant, Trade name: Septoquat AM MD & Septoquat AM MD RFU, Alternative Trade Name: Alkadez Quat AM MD (North Macedonia), Variants: 750 ml, 1L, 3L, 5L and 10L	MDD Certificate BG19/871876;	N/A	<input checked="" type="checkbox"/> 31 December 2028	N/A	LOT no.: Septoquat AM MD 196  RFU 030



Disinfectant, Trade name: Aldesept MD Variants: 250 ml, 500 ml, 1L, 3L and 5L	MDD Certificate BG19/871876;	N/A	<input checked="" type="checkbox"/> 31 December 2028	N/A	LOT no.: 285
Disinfectant, Trade name: Citricadez 20% and Citricadez 50% Alternative trade names: Diacitral 20% MD and Diacitral 50% MD (North Macedonia) Variants: 5L and 10L	MDD Certificate BG19/871876;	N/A	<input checked="" type="checkbox"/> 31 December 2028	N/A	LOT no.: Citricadez 50% 145  Citricadez 20% 143
Disinfectant, Trade name: Zhivasept Rapid MD, Alternative trade names: Alkadez Rapid MD (North Macedonia) Variants: 750 ml, 1L, 3L, 5L and 10L	MDD Certificate BG19/871876;	N/A	<input checked="" type="checkbox"/> 31 December 2028	N/A	LOT no.: 227

**Appendix 2 – Traceability table - identification number of OUTGOING NB to the number of 3EC**

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



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

**ADDENDUM No. <x>  
to the  
TRANSFER AGREEMENT Ref. :**

**coming into force on <date>**

between

**<customer name>  
- "Certification Holder" - ,**

**<new NB name>  
- "3EC" -, and**

**<previous NB name>  
- "OUTGOING NB" -**

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

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

MDD/AIMDD Device name or REF	MDD/AIMDD Certificate Reference(s) of the MDD/AIMDD device	Is the device under MDR replaced (substituted) with another device – please identify the corresponding substitute device	Maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU 2023/607)	Imposed restrictions on the valid and not- suspended certificate or other relevant information	The last serial number or lot number for which the outgoing notified body is responsible (see § 3 (5a))
<b>Device 1</b>	Certificate # incl. Rev.	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> 31 December 2027 <input type="checkbox"/> 31 December 2028		
<b>Device 2</b>	Certificate # incl. Rev.	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding substitute device under MDR	<input type="checkbox"/> 31 December 2027 <input type="checkbox"/> 31 December 2028		

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

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

17-Jul-24; Sofia, Bulgaria

<place, date>

Damian  
Plamenov  
Kambourov  
v

<name> Damian Kambourov  
<position> Managing Director

Agreed on behalf of  
**3EC :**

18-Jul-2024, Bratislava

<place, date>

Agreed on behalf of  
**OUTGOING NB :**

16-Jul-24

<place, date>

DocuSigned by:

<name> Geoffrey De Visscher  
<position> Head of Notified Body 1639

**3EC International a.s.** ①  
Hraničná 18, 821 05 Bratislava  
Slovenská republika  
IČO: 36 789 003  
IČ DPH: SK2022390073