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Memo on the extension of the validity of the CE Certificate of PV .035

The purpose of this memo is to document the extension of the validity of the certificate CE 742557, assigned to the medical device "Visions Ultrasound Catheter PV. 035", with reference number 88901, following the fulfillment of the criteria set out in the Article 120 of the Regulation (EU) 2023/607 published on the European Union Official Journal on 20th March 2023.

On 20th March 2023, the European Union implemented the Regulation (EU) 2023/607, which amended the Regulation (EU) 2017/745 (MDR) and set new criteria for the transitional provisions of Article 120.

Volcano Corporation, acquired by Philips in 2015 on its assessment as manufacturer of the medical device "Visions Ultrasound Catheter PV. 035", hereby confirms that the device Certificate CE 742557, previously expired on 15th August 2022, does meet all the new requirement outlined in the transitional provisions of Article 120 of the Regulation (EU) 2023/607 published on the European Union and therefore its validity is extended until 31st December 2027.

For your convenience, in the table depicted in Annex 1, the Manufacturer assessment of compliance with the criteria of Article 120 is outlined.

In summary, the medical device "Visions Ultrasound Catheter PV. 035", with reference number 88901 carries a valid certificate (i.e: CE 742557) until 31st December 2027. Consequently, the supply of this medical device is resumed.

Date and Signature

Director Regulatory Affairs

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Annex 1: Manufacturer assessment of compliance with the criteria of Article 120

	Art 120.3c (a): those devices continue to **comply with** Directive 90/385/EEC or **Directive 93/42/EEC**, as applicable	Art 120.3c (b): there **are no significant changes in the design and intended purpose**	Art 120.3c (c.): the devices **do not present an unacceptable risk to the health or safety** of patients, users or other persons, or to other aspects of the protection of public health;	Art.120 3c (d): no later than 26 May 2024, the manufacturer has put in place a **quality management system in accordance with Article 10(9)**[i];	Art.120 3c (e): no later than 26 May 2024, the manufacturer or the authorised representative has lodged a **formal application with a notified body** in accordance with Section 4.3, first subparagraph, of Annex VII[ii] **for conformity assessment** in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device,	Art.120 3c (e): and, no later than 26 September 2024, **the notified body and the manufacturer have signed a written** agreement in accordance with Section 4.3, second subparagraph, of Annex VII[iii].	Art. 120 3d.: By way of derogation from paragraph 3 of this Article, the requirements of this Regulation relating to **post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices** shall apply to devices referred to in paragraphs 3a and 3b of this Article in place of the corresponcing requirements in Directives 90/385/EEC and 93/42/EEC.	Art 120 3e.: Without prejudice to Chapter IV[iv] and paragraph 1[v] of this Article, **the notified body that issued the certificate** referred to in paragraph 3a of this Article **shall continue to be responsible for the appropriate surveillance** in respect of the applicable requirements relating to the devices it has certified, unless the manufacturer has agreed with a notified body designated in accordance with Article 42[vi] that the latter shall carry out such surveillance.	120.2.(a): Certificates issued by notified bodies in accordance with those Directives from 25 May 2017 that were still valid on 26 May 2021 and that have expired before ... [20 March 2023] shall be considered to be valid until the dates set out in paragraph 3a of this Article only **if one of the following conditions is fulfilled:** (a) **before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement** in accordance with Section 4.3, second subparagraph, of Annex VII[vii] to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device; (b) **a competent authority of a Member State has granted a derogation** from the applicable conformity assessment procedure in accordance with Article 59(1)[viii] of this Regulation or has required the manufacturer, in accordance with Article 97(1)[ix] of this Regulation, to carry out the applicable conformity assessment procedure.	Art.120.3a. Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates: (a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors; (b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.
"Visions Ultrasound Catheter PV. 035", with reference number 88901 Class III catheter	Yes	Yes	Yes	Yes MDR Quality Management System (QMS) Certificate 731459	Yes technical file submitted in October 2020	Yes agreement between BSI and Philips signed on 5th June 2020	Yes	Yes Keep working with BSI	Yes CE 742557 expired 15 Aug 2022	31 Dec 2027

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[i] REGULATION (EU) 2017/745, Art 10.9: *" Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in device design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner. Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device. The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation. The quality management system shall address at least the following aspects:*
(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;
(b) identification of applicable general safety and performance requirements and exploration of options to address those requirements;
(c) responsibility of the management;
(d) resource management, including selection and control of suppliers and sub-contractors;
(e) risk management as set out in in Section 3 of Annex I; (f) clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF;
(g) product realisation, including planning, design, development, production and service provision;
(h) verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29;
(i) setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83;
(j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;
(k) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;
(l) management of corrective and preventive actions and verification of their effectiveness;
(m) processes for monitoring and measurement of output, data analysis and product improvement."

[ii] REGULATION (EU) 2017/745, Section 4.3, second subparagraph, of Annex VII : *"The contract between a notified body and a manufacturer shall take the form of a written agreement signed by both parties. It shall be kept by the notified body. This contract shall have clear terms and conditions and contain obligations that enable the notified body to act as required under this Regulation, including an obligation on the manufacturer to inform the notified body of vigilance reports, the right of the notified body to suspend, restrict or withdraw certificates issued and the duty of the notified body to fulfil its information obligations."*

[iii] REGULATION (EU) 2017/745, Section 4.3, second subparagraph, of Annex VII : *"The contract between a notified body and a manufacturer shall take the form of a written agreement signed by both parties. It shall be kept by the notified body. This contract shall have clear terms and conditions and contain obligations that enable the notified body to act as required under this Regulation, including an obligation on the manufacturer to inform the notified body of vigilance reports, the right of the notified body to suspend, restrict or withdraw certificates issued and the duty of the notified body to fulfil its information obligations."*

[iv] REGULATION (EU) 2017/745, *CHAPTER IV: NOTIFIED BODIES*

[v] REGULATION (EU) 2017/745, Art. 120, First paragraph: *"From 26 May 2021, any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void."*

[vi] REGULATION (EU) 2017/745, Art. 42 *"Designation and notification procedure*
1. Member States may only designate conformity assessment bodies for which the assessment pursuant to Article 39 was completed and which comply with Annex VII.
2. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool within the database of notified bodies developed and managed by the Commission (NANDO).
3. The notification shall clearly specify, using the codes referred to in paragraph 13 of this Article, the scope of the designation indicating the conformity assessment activities as defined in this Regulation and the types of devices which the notified body is authorised to assess and, without prejudice to Article 44, any conditions associated with the designation. 5.5.2017 EN Official Journal of the European Union L 117/43
4. The notification shall be accompanied by the final assessment report of the authority responsible for notified bodies, the final opinion of the joint assessment team referred to in Article 39(9) and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.
5. The notifying Member State shall, without prejudice to Article 44, inform the Commission and the other Member States of any conditions associated with the designation and provide documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VII.
6. Within 28 days of the notification referred to in paragraph 2, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the authority responsible for notified bodies. Where no objection is raised, the Commission shall publish in NANDO the notification within 42 days of its having been notified as referred to in paragraph 2.
7. When a Member State or the Commission raises objections in accordance with paragraph 6, the Commission shall bring the matter before the MDCG within 10 days of the expiry of the period referred to in paragraph 6. After consulting the parties involved, the MDCG shall give its opinion at the latest within 40 days of the matter having been brought before it. Where the MDCG is of the opinion that the notification can be accepted, the Commission shall publish in NANDO the notification within 14 days.
8. Where the MDCG, after having been consulted in accordance with paragraph 7, confirms the existing objection or raises another objection, the notifying Member State shall provide a written response to the MDCG opinion within 40 days of its receipt. The response shall address the objections raised in the opinion, and set out the reasons for the notifying Member State's decision to designate or not designate the conformity assessment body.
9. Where the notifying Member State decides to uphold its decision to designate the conformity assessment body, having given its reasons in accordance with paragraph 8, the Commission shall publish in NANDO the notification within 14 days of being informed thereof.
10. When publishing the notification in NANDO, the Commission shall also add to the electronic system referred to in Article 57 the information relating to the notification of the notified body along with the documents mentioned in paragraph 4 of this Article and the opinion and responses referred to in paragraphs 7 and 8 of this Article.
11. The designation shall become valid the day after the notification is published in NANDO. The published notification shall state the scope of lawful conformity assessment activity of the notified body.

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12. The conformity assessment body concerned may perform the activities of a notified body only after the designation has become valid in accordance with paragraph 11. 13. The Commission shall by 26 November 2017, by means of implementing acts, draw up a list of codes and corresponding types of devices for the purpose of specifying the scope of the designation of notified bodies. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). The Commission, after consulting the MDCG, may update this list based, inter alia, on information arising from the coordination activities described in Article 48."

[vii] REGULATION (EU) 2017/745, Section 4.3, second subparagraph, of Annex VII : *"The contract between a notified body and a manufacturer shall take the form of a written agreement signed by both parties. It shall be kept by the notified body. This contract shall have clear terms and conditions and contain obligations that enable the notified body to act as required under this Regulation, including an obligation on the manufacturer to inform the notified body of vigilance reports, the right of the notified body to suspend, restrict or withdraw certificates issued and the duty of the notified body to fulfil its information obligations."*

[viii] REGULATION (EU) 2017/745, Art. 59 *"Derogation from the conformity assessment procedures*
1. By way of derogation from Article 52, any competent authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the procedures referred to in that Article have not been carried out but use of which is in the interest of public health or patient safety or health.
2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient. 3. Following a notification pursuant to paragraph 2 of this Article, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a limited period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 of this Article to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 114(4)."

[ix] REGULATION (EU) 2017/745, Art. 97 *"Other non-compliance*
1. Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non compliance.
2. Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph 1 of this Article, the Member State concerned shall, without delay, take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States, without delay, of those measures, by means of the electronic system referred to in Article 100.
3. In order to ensure the uniform application of this Article, the Commission may, by means of implementing acts, specify appropriate measures to be taken by competent authorities to address given types of non-compliance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3)."

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