VATECH Co., Ltd.
13, Samsung 1-ro 2-gil,
Hwaseong-si, Gyeonggi-do,
18449, Korea

Statement on CE MDD Extension

VATECH Co., Ltd.

Date: May 24th 2024

To whom it may concern,

Legacy devices should be understood as devices, which, in accordance with Article 120(3) of the MDR, are placed on the market after the MDR's date of application (DoA) and until 26 May 2024 if certain conditions are fulfilled. Those devices can be:

- devices which are class I devices under Directive 93/42/EEC (MDD), for which an EC declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a notified body;
- devices covered by a valid EC certificate issued in accordance with Directive 90/385/EEC (AIMDD) or the MDD prior to 26 May 2021.

(According to the Terminology of 'Legacy devices' in MDCG 2021-25)

Regulation (EU) 2023/607 was published in 2023 to provide a more extensive and far-reaching amendment to Article 120 which contains Transitional Provisions to provide a period of grace for devices (Legacy devices) which are compliant with the EU Medical Device Directive 93/42/EEC (MDD) or the EU Active Implantable Medical Device Directive 90/385/EEC (AIMDD).

According to this,

The extension of the transitional period and the concomitant extension of the certificate's validity is done automatically by law, provided the conditions laid down in Article 120(3c) MDR are fulfilled.
(a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;
(b) there are no significant changes in the design and intended purpose;
(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;
(d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);
(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 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, 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.

In addition, according to Q&A No.7 of Part B (EVIDENCE OF EXTENDED TRANSITIONAL PERIOD) of the Q&A document issued by the European Commission regarding MDR extension, it is explained that manufacturers can provide proof of extension through 'Self-declaration'.

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'The manufacturer should be able to provide a self-declaration confirming that the conditions for the extension are fulfilled, stating the end date of the transition period. Such self-declaration could be based on a harmonised template. Such self-declaration should clearly identify the devices covered by the extension and certificates concerned.'

Which means, it allowed VATECH legacy devices1 to continue being placed on the EU market up until 31 December 2028 even though the expiration date on EC Certificate is 26 May 2024.

VATECH legacy devices1 - Cert#: 10877-2017-CE-KOR-NA-PS Rev.3.0 /NB Identification: DNV Product Assurance AS (NB 2460)

VATECH Co., Ltd. hereby to demonstrate that VATECH legacy devices comply with all the current MDR Regulations.

Attachment 1 : Manufacturer`s Self-Declaration (No. DMSP-5-PA-MDR-32 A2)

2024. 05.24

KIM SANGMIN *Date*

PRRC(Person Responsible for Regulatory Compliance) of **VATECH Co., Ltd.**