Notified Body Confirmation Letter Reference: C647306

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework 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

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Vitrolife Sweden AB
Gustaf Werners Gata 2
SE-421 32 Västra Frölunda
Sweden

SRN Number (if available): SE-MF-000002389

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 2023.10.19

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ASP™ / 735002591AAADA	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
EmbryoGlue® /735002591AABDC	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
FreezeKit™ Cleave / 735002591ABFDP	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
ThawKit™ Cleave / 735002591ABHDT	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
G-1™ PLUS / 735002591AACDE	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
G-2™ PLUS / 735002591AADDG	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
G-GAMETE™ / 735002591AAEDJ	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
G-IVF™ PLUS / 735002591AAFDL	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
G-MOPS™ / 735002591AAHDQ	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
G-MOPS™ PLUS / 735002591AAHDQ	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
G-PGD™ / 735002591AASEE	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
G-RINSE™ / 735002591AAJDU	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
G-TL™ / 735002591AAKDW	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
HSA-solution™ / 735002591AALDY	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
HYASE™-10X / 735002591AAME2	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
ICSI™ /	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
735002591AANE4			241688-2017-CE-NOR-NA-PS Rev. 4.0
OVOIL™ / 735002591AAOE6	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0
OVOIL HEAVY™ / 735002591AAOE6	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0
RapidWarm™ Blast / 735002591AAVEL	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
RapidWarm™ Cleave / 735002591AAXEQ	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
RapidWarm™ Omni / 735002591AAZEU	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
RapidWarm™ Oocyte / 735002591ABBDF	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
RapidVit™ Blast / 735002591AAUEJ	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
RapidVit™ Cleave / 735002591AAWEN	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
RapidVit™ Omni / 735002591AAYES	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
RapidVit™ Oocyte / 735002591ABADD	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
SpermFreeze Solution™ / 735002591ABCDH	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0
SpermGrad™ / 735002591ABDDK	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0
SpermRinse™ / 735002591ABEDM	Class III	NA	246961-2017-CE-NOR-NA-PS Rev. 4.0 241688-2017-CE-NOR-NA-PS Rev. 4.0

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not Applicable	Not Applicable	Not Applicable	Not Applicable

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/10/19	C647306	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607
- Significant changes to design or intended purpose of the devices
- Changes in the quality system affecting production
- Periodical audits not held within the timeframe