Digitally signed by Perminov Andrei
Date: 2025.06.02 13:43:27 EEST
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Notified Body Confirmation Letter Reference: C636433

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:

Cupid Limited

A-68, MIDC, (Malegaon), Sinnar, Nashik- 422 113, Maharashtra, India

SRN Number: IN-MF-000033199

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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, 2023/10/17

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

André Fernandes
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:

<table>
<tr><th>Device name and Basic UDI-DI (under MDR application)</th><th>MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)</th><th>If the MDR device is a substitute device, identification of the corresponding MDD device</th><th>MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</th></tr>
<tr><td>Device name:
Male Condom
Basic UDI-DI:
890600528cup1UL
Variants:
<table>
<tr><th rowspan="2">Sr. No</th><th rowspan="2">Model / Type</th><th rowspan="2">Length (mm)</th><th rowspan="2">Width (mm)</th><th rowspan="2">Thickness (mm)</th><th rowspan="2">Lubricant (Mg.)</th><th colspan="2">One or More & With or Without below Additives</th></tr>
<tr><th>Colour</th><th>Flavours</th></tr>
<tr><td>1</td><td>Plain</td><td>NLT 170.0</td><td>47 to 51</td><td>0.045 to 0.075</td><td rowspan="8">min. 250 or 550 ± 150</td><td rowspan="8">up to 0.05 % of compounded latex.</td><td rowspan="8">up to 3 % the Quantity of Lubricant used</td></tr>
<tr><td>2</td><td>Plain</td><td>NLT 180.0</td><td>51 to 55</td><td>0.045 to 0.075</td></tr>
<tr><td>3</td><td>Plain (Thin)</td><td>NLT 180.0</td><td>51 to 55</td><td>0.040 to 0.060</td></tr>
<tr><td>4</td><td>Plain (Thick)</td><td>NLT 180.0</td><td>51 to 55</td><td>0.080 to 0.12</td></tr>
<tr><td>5</td><td>Plain (Large)</td><td>NLT 190.0</td><td>54 to 58</td><td>0.045 to 0.075</td></tr>
<tr><td>6</td><td>Dotted</td><td>NLT 180.0</td><td>51 to 55</td><td>0.045 to 0.075</td></tr>
<tr><td>7</td><td>Ribbed</td><td>NLT 180.0</td><td>51 to 55</td><td>0.045 to 0.075</td></tr>
<tr><td>8</td><td>Plain, Dotted, Contour & Ribbed</td><td>NLT 180.0</td><td>51 to 55</td><td>0.045 to 0.075</td></tr>
</table>
Brand Names: NA</td><td>IIb</td><td>NA</td><td>MDD certificate Number: 263814-2018-CE-IND-NA-PS
NoBo Number: 02460
NoBo Name: DNV Product Assurance AS
Appendix Rev. 0 Certificate 263814-2018-CE-IND-NA-PS
Appendix Rev. 0 Certificate 263815-2018-CE-IND-NA-PS</td></tr>
</table>

<table>
<tr><th>Device name and Basic UDI-DI (under MDR application)</th><th>MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)</th><th>If the MDR device is a substitute device, identification of the corresponding MDD device</th><th>MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</th></tr>
<tr><td>Device name:
Female Condom
Basic UDI-DI:
890600528cup4US
Variants:
FEMALE CONDOM VARIANTS:
<table>
<tr><th rowspan="2">Description</th><th colspan="3">Product Variant Codes</th></tr>
<tr><th>F1</th><th>F2</th><th>F3</th></tr>
<tr><td>DEVICE AVERAGE LENGTH (in mm)</td><td>145.0 -165.0</td><td>125.0 -145.0</td><td>145.0 -165.0</td></tr>
<tr><td colspan="4">SHEATH/POUCH:</td></tr>
<tr><td>AVERAGE WIDTH (in mm)</td><td>73.0 - 77.0</td><td>73.0 - 77.0</td><td>73.0 - 77.0</td></tr>
<tr><td>AVERAGE THICKNESS (in mm)</td><td>0.09 - 0.12</td><td>0.09 - 0.12</td><td>0.09 - 0.12</td></tr>
<tr><td>MATERIAL OF CONSTRUCTION</td><td>NRL</td><td>NRL</td><td>NRL</td></tr>
<tr><td>COLOUR</td><td>NATURAL/COLOUR</td><td>NATURAL/COLOUR</td><td>NATURAL/COLOUR</td></tr>
<tr><td colspan="4">EXTERNAL RETAINER:</td></tr>
<tr><td>- SHAPE</td><td>OCTAGON</td><td>OCTAGON</td><td>OCTAGON</td></tr>
<tr><td>- AVERAGE OUTER DIA. (in mm)</td><td>70.0 - 80.0</td><td>70.0 - 80.0</td><td>70.0 - 80.0</td></tr>
<tr><td>- AVERAGE THICKNESS (in mm)</td><td>1.5 - 2.5</td><td>1.5 - 2.5</td><td>1.5 - 2.5</td></tr>
<tr><td>- AVERAGE FACE WIDTH</td><td>2.0 - 4.0</td><td>2.0 - 4.0</td><td>2.0 - 4.0</td></tr>
<tr><td>- COLOUR</td><td>NATURAL/WHITE</td><td>NATURAL/WHITE</td><td>NATURAL/WHITE</td></tr>
<tr><td>- MATERIAL OF CONSTRUCTION</td><td>LDPE</td><td>LDPE</td><td>LDPE</td></tr>
<tr><td colspan="4">INTERNAL RETAINER:</td></tr>
<tr><td>- SHAPE</td><td>DONUT</td><td>DONUT</td><td>CIRCULAR RING</td></tr>
<tr><td>- AVERAGE OUTER DIA. (in mm)</td><td colspan="3">47.0 - 53.0</td></tr>
<tr><td>- AVERAGE</td><td>7.0 - 13.0</td><td>7.0 - 13.0</td><td>37.0 - 43.0</td></tr>
</table></td><td>IIb</td><td>NA</td><td>MDD certificate Number: 263815-2018-CE-IND-NA-PS
NoBo Number: 02460</td></tr>
</table>

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
<table><tr><td>INNER DIA. (in mm)</td><td></td><td></td><td></td></tr><tr><td>- AVERAGE THICKNESS (in mm)</td><td>22.0 - 28.0</td><td>11.0 - 13.0</td><td>4.0 - 7.0</td></tr><tr><td>- COLOUR</td><td colspan="3">NATURAL/WHITE/OTHER COLOURS</td></tr><tr><td>- MATERIAL OF CONSTRUCTION</td><td colspan="2">POLYURETHANE OPEN CELL FOAM</td><td>POLYURETHANE</td></tr><tr><td>**LUBRICATION**</td><td colspan="3">SILICONE OIL - Quantity: 750 - 1050 Mg</td></tr><tr><td>**FLAVOUR**</td><td colspan="3">WITH OR WITHOUT FLAVOURS - up to 3% of Quantity of Lubricant</td></tr></table> NRL- NATURAL RUBBER LATEX LDPE - LOW DENSITY POLY ETHYLENE Brand Names: NA			

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
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/10/17	C636433	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

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
263814-2018-CE-IND-NA-PS Rev 1.0	**PRJC-544565-2016-MSL-IND**	**05 November 2023**

This is to certify that the quality system of:

Cupid Limited
A-68, M.I.D.C. (Malegaon), Sinnar, Nashik - 422 113, Maharashtra, INDIA.

For design, production and final product inspection/testing of:

Contraceptives.

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 22 October 2019

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Tone Kolpus

Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

A DNV GL COMPANY

Certificate No.:	Project No.:	Valid Until:
263814-2018-CE-IND-NA-PS Rev 1.0	**PRJC-544565-2016-MSL-IND**	**05 November 2023**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original certificate	2018-11-05
1.0	**EU Representative Change**	2019-10-22

Products covered by this Certificate:

Product Description	Product Name	Class
Male Latex Condoms	Male Condom: Varieties	IIb

Sr. No.	Model / Type	Length (mm)	Width (mm)	Thickness (mm)	Lubricant (Mg.)	One or More & With or Without below Additives	
						Colour	Flavours
1	Plain	NLT 170.0	47 to 51	0.045 to 0.075	min. 250 or 550 ± 150	up to 0.05 % of compounded latex.	up to 3 % the Quantity of Lubricant used
2	Plain	NLT 180.0	51 to 55	0.045 to 0.075			
3	Plain (Thin)	NLT 180.0	51 to 55	0.040 to 0.060			
4	Plain (Thick)	NLT 180.0	51 to 55	0.080 to 0.12			
5	Plain (Large)	NLT 190.0	54 to 58	0.045 to 0.075			
6	Plain (Long)	NLT 200.0	51 to 55	0.045 to 0.075			
7	Dotted	NLT 180.0	51 to 55	0.045 to 0.075			
8	Ribbed	NLT 180.0	51 to 55	0.045 to 0.075			
9	Plain, Dotted, Contour & Ribbed	NLT 180.0	51 to 55	0.045 to 0.075			
10	Dotted & Contour	NLT 180.0	51 to 55	0.045 to 0.075			
11	Ribbed & Contour	NLT 180.0	51 to 55	0.045 to 0.075			
12	Plain & Flaired	NLT 180.0	51 to 55	0.045 to 0.075			
13	Dotted & Ribbed	NLT 180.0	51 to 55	0.045 to 0.075			

NLT - Not Less Than

The complete list of devices is filed with the Notified Body

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
263814-2018-CE-IND-NA-PS Rev 1.0	**PRJC-544565-2016-MSL-IND**	**05 November 2023**

Sites covered by this certificate

Site Name	Address
Cupid Limited	A-68, M.I.D.C. (Malegaon), Sinnar, Nashik - 422 113, Maharashtra, INDIA.

EU Representative

OBELIS S.A

Registered Address: Bd. Général Wahis, 53, 1030 Brussels, Belgium

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate