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CooperSurgical, Inc.

95 Corporate Drive
Trumbull
Connecticut
06611
USA

20th May 2024

Notified Body Confirmation Letter

Reference: EU2023-607/715345

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** 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:

CooperSurgical, Inc.

95 Corporate Drive
Trumbull
Connecticut
06611
USA

SRN Number: US-MF-000002607

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 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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.

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)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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 or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
LoneStar Sterile Retractors	Class I device placed on the market in sterile condition	N/A	CE 69386; NB 2797
Cytology Sampling Devices	Class I device placed on the market in sterile condition	N/A	CE 69386; NB 2797
Pipelle	Class I device placed on the market in sterile condition	N/A	CE 69386; NB 2797
Wallach Endocell Endometrial Cell Sampler	Class I device placed on the market in sterile condition	N/A	CE 69386; NB 2797
Hysterosalpingography Catheter	Class I device placed on the market in sterile condition	N/A	CE 69386; NB 2797
Intrauterine Insemination Catheters	Class I device placed on the market in sterile condition	N/A	CE 69386; NB 2797
Assisted Reproductive Catheters	Class I device placed on the market in sterile condition	N/A	CE 69386; NB 2797
Sterile Adapter Drapes	Class I device placed on the market in sterile condition	N/A	CE 69386; NB 2797
Pipet Curet	Class I device placed on the market in sterile condition	N/A	CE 69386; NB 2797
Fetal Pillow	Class I device placed on the market in sterile condition	N/A	GB 19/964706; NB 1693
Disposable Vaginal Speculum	Class I device placed on the market in sterile condition	N/A	CE 575867; NB 2797
Endoscopic Seal	Class I device placed on the market in sterile condition	N/A	CE 575867; NB 2797
IVF Pasteur Pipettes	Class IIa	N/A	CE 69386; NB 2797
LoneStar Retractor Systems (AMS, Colorectal, Gynecology)	Class IIa	N/A	CE 69386; NB 2797
Uterine Manipulators/Injectors and Accessories (sterile single use, non-sterile re-usable)	Class IIa	N/A	CE 69386; NB 2797
Secondary Cannula/ Trocar Devices	Class IIa	N/A	CE 69386; NB 2797
LoneStar Sterile Stays	Class IIa	N/A	CE 69386; NB 2797

Device name or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Fetal Vacuum Extraction System and Accessories	Class IIa	N/A	CE 69386; NB 2797
Medical Heat Packs	Class IIa	N/A	CE 69386; NB 2797
Ultrasound Dopplers	Class IIa	N/A	CE 69386; NB 2797
TPC Micropipettes	Class IIa	N/A	CE 69386; NB 2797
Origio Micropipettes	Class IIa	N/A	CE 69386; NB 2797
Wallace Oocyte Recovery Set	Class IIa	N/A	CE 69386; NB 2797
EndoSee Hysteroscope and Cannula	Class IIa	N/A	CE 69386; NB 2797
IVF Incubators	Class IIa	N/A	CE 69386; NB 2797
RI Integra Micromanipulator	Class IIa	N/A	CE 735275; NB 2797
RI Witness Embryology Heated Plate	Class IIa	N/A	CE 735275; NB 2797
Liquid Paraffin	Class IIa	N/A	CE 733551; NB 2797
VitriFit™	Class IIa	N/A	CE 733551; NB 2797
IVF Media (Oil)	Class IIa	N/A	CE 550877; NB 2797
ART Dishes	Class IIa	N/A	CE 550877; NB 2797
Oil For Tissue Culture	Class IIa	N/A	CE 82107; NB 2797
Carter-Thomason CloseSure System	Class IIa	N/A	CE 69386; NB 2797
Carter-Thomason® II Port Closure System Suture Passer	Class IIa	N/A	CE 69386; NB 2797
Milex Pessaries	Class IIb excluding Class IIb implantable non-WET	N/A	CE 69386; NB 2797
LEEP Electrodes	Class IIb excluding Class IIb implantable non-WET	N/A	CE 82107; NB 2797
Fischer® Cone Biopsy Excisor	Class IIb excluding Class IIb implantable non-WET	N/A	CE 82107; NB 2797
Milex and Wallace Pessaries	Class IIb excluding Class IIb implantable non-WET	N/A	CE 82107; NB 2797
STRIPPER Tips	Class IIb excluding Class IIb implantable non-WET	N/A	CE 69386; NB 2797

Device name or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
TPC Micropipettes	Class IIb excluding Class IIb implantable non-WET	N/A	CE 69386; NB 2797
Origio Micropipettes	Class IIb excluding Class IIb implantable non-WET	N/A	CE 69386; NB 2797
EZ-Range (EZ-Tip, EZ-Strip, EZ-Squeeze) sterile single-use plastic pipettes	Class IIb excluding Class IIb implantable non-WET	N/A	CE 735275; NB 2797
RI Saturn Laser System	Class IIb excluding Class IIb implantable non-WET	N/A	CE 735275; NB 2797
Hyaluronan binding sperm selection device (PICSI)	Class III	N/A	CE 82107; NB 2797
INSORB Stapler and Absorbable Staples	Class III	N/A	CE 90952; NB 2797 CE 99616; NB 2797
SAGE 1-Step™	Class III	N/A	CE 733551; NB 2797 CE 733555; NB 2797
ORIGIO® Sperm Wash	Class III	N/A	CE 733551; NB 2797 CE 733556; NB 2797
ORIGIO® Sequential Fert™	Class III	N/A	CE 733551; NB 2797 CE 733557; NB 2797
ORIGIO® Sequential Cleav™	Class III	N/A	CE 733551; NB 2797 CE 733557; NB 2797
ORIGIO® Sequential Blast™	Class III	N/A	CE 733551; NB 2797 CE 733557; NB 2797
ORIGIO® Gradient™ 90	Class III	N/A	CE 733551; NB 2797 CE 733558; NB 2797
ORIGIO® Gradient™ 40/80	Class III	N/A	CE 733551; NB 2797 CE 733558; NB 2797
Medicult Vitrification Cooling	Class III	N/A	CE 733551; NB 2797 CE 733559; NB 2797
MediCult Vitrification Warming	Class III	N/A	CE 733551; NB 2797 CE 733559; NB 2797
Biopsy medium	Class III	N/A	CE 733551; NB 2797

Device name or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			CE 733560; NB 2797
BlastFreeze™	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
BlastThaw™	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
CryoSperm™	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
Embryo Freezing Pack	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
Embryo Thawing Pack	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
Flushing Medium	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
ICSI Cumulase®	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
MediCult IVM® System	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
PVP Clinical Grade	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
PVP Medium	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
Sperm Freezing Medium	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
Sperm Preparation Medium	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
SpermSlow™	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
SynVitro® Flush	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
Universal IVF Medium	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797

Device name or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
UTM™ Transfer Medium	Class III	N/A	CE 733551; NB 2797 CE 733560; NB 2797
EmbryoGen®	Class III	N/A	CE 733551; NB 2797 CE 733561; NB 2797
BlastGen™	Class III	N/A	CE 733551; NB 2797 CE 733561; NB 2797
ORIGIO® Handling™	Class III	N/A	CE 733551; NB 2797 CE 744875; NB 2797
ORIGIO® Gradient™ 100	Class III	N/A	CE 733551; NB 2797
LG global	Class III	N/A	CE 550887; NB 2797 CE 549386; NB 2797
LG global for Fertilization	Class III	N/A	CE 550887; NB 2797 CE 549386; NB 2797
LG global w/ HEPES	Class III	N/A	CE 550887; NB 2797 CE 549386; NB 2797
LG global collect	Class III	N/A	CE 550887; NB 2797 CE 549386; NB 2797
LG global total LP	Class III	N/A	CE 550887; NB 2797 CE 549386; NB 2797
LG global total LP w/ HEPES	Class III	N/A	CE 550887; NB 2797 CE 549386; NB 2797
LG global total LP for Fertilization	Class III	N/A	CE 550887; NB 2797 CE 549386; NB 2797
HSA	Class III	N/A	CE 550887; NB 2797 CE 549386; NB 2797
Quinn's® Sperm Washing Medium	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797
Quinn's Advantage™ Protein Plus Fertilization (HTF) Medium	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797
PVP™ 7% Ready to Use Solution Kit	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797

Device name or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Quinn's Advantage™ Thaw Kit	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797
Quinn's Advantage™ Sperm Freezing Medium	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797
Sage™ Vitrification Kit	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797
Sage™ Vitrification Warming Kit	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797
Human Serum Albumin	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797
Quinn's Advantage™ Fertilization (HTF) Medium	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797
Quinn's Advantage™ Medium with HEPES	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797
Quinn's Advantage™ Cleavage Medium	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797
Quinn's Advantage™ Blastocyst Medium	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797
PureCeption™ 24-determination Kit	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797
PureCeption™ 40% Upper Phase	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797
PureCeption™ 80% Lower Phase	Class III	N/A	CE 82107; NB 2797 CE 551319; NB 2797

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

Device name or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Cervical Sizer	Class I device with a measuring function	N/A	N/A - Device did not require a Notified Body certificate under Directives
LoneStar Reusable Retractors	Class I device that qualifies as a re-usable surgical instrument	N/A	N/A - Device did not require a Notified Body certificate under Directives
STRIPPER Accessories	Class IIb excluding Class IIb implantable non-WET	N/A	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	Action
2023/10/27	Initial issue
2023/11/16	Correction to certificate numbers for SAGE 1-Step™ and ORIGIO® Sperm Wash
2024/02/22	Correction to spelling of 'Inorb Stapler and Absorbable Staples' Addition of Carter-Thomason CloseSure System and Carter-Thomason® II Port Closure System Suture Passer to Table 1 MDR classification of Cervical Sizer amended to remove 'Class Ir' Removal of Milex Pessary Fitting Kit Name amendment for 'K-Systems G210 InviCell Long Term Incubator' to 'IVF Incubators'
2024/03/06	Transfer of letter onto new letter template Correction to spelling of 'INSORB Stapler and Absorbable Staples'
2024/04/03	Removal of Acidified Tyrodes Solution from Table 1
2024/05/20	Addition of Pipette Curet, Fetal Pillow, Disposable Vaginal Speculum & Endoscopic Seal to Table 1 Addition of LoneStar Reusable Retractors to Table 2