Notified Body Confirmation Letter Reference: C627818

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:

Coloplast A/S
Holtedam 1
3050 Humlebæk
Denmark

SRN Number: DK-MF-000025526

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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, 02.09.2024

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
Biatain Ibu Non-Adhesive foam dressing 57089322853047J	Class III	NA	10000410282-PA-NA-DNK EC Design Examination Certificate no: 10000410284-PA-NA-DNK
Biatain Ibu Soft-Hold foam dressing 57089322853057L	Class III	NA	10000410282-PA-NA-DNK EC Design Examination Certificate no: 10000410284-PA-NA-DNK
InterDry wicking fabric 57089322853167R	Class III	NA	10000410282-PA-NA-DNK EC Design Examination Certificate no.: 10000423479-PA-NA-DNK
Comfeel Plus hydrocolloid dressing 57089322853067N	Class IIb	NA	10000410282-PA-NA-DNK
Comfeel Plus Transparent hydrocolloid dressing 57089322853077Q	Class IIb	NA	10000410282-PA-NA-DNK
Comfeel Plus Contour hydrocolloid dressing 57089322853097U	Class IIb	NA	10000410282-PA-NA-DNK
Biatain Superabsorber non-adhesive dressing	Class IIb	Biatain Super Adhesive dressing	10000410282-PA-NA-DNK

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
5708932123537621JL		Biatain Super Non-Adhesive dressing	
Biatain Adhesive foam dressing 57089322852988G	Class IIb	NA	10000410282-PA-NA-DNK
Biatain Non-Adhesive foam dressing 57089322852978E	Class IIb	NA	10000410282-PA-NA-DNK
Biatain Silicone foam dressing 57089322853027E	Class IIb	NA	10000410282-PA-NA-DNK
Biatain Silicone Lite foam dressing 57089322853037G	Class IIb	NA	10000410282-PA-NA-DNK
Biatain Silicone Non-Border foam dressing 570893260292393Q2	Class IIb	NA	10000410282-PA-NA-DNK
Biatain Silicone against pressure injuries 57089322853017C	Class IIb	NA	10000410282-PA-NA-DNK
Purilon Gel 57089322853157P	Class IIb	NA	10000410282-PA-NA-DNK
Biatain Fiber dressing 57089322853147M	Class IIb	NA	10000410282-PA-NA-DNK
Conseal Plug 5708932117220516H4	Class IIb	NA	10000410282-PA-NA-DNK
Peristeen Anal Plug and accessories 57089322978619G	Class IIb	NA	10000410282-PA-NA-DNK
SenSura Mio Baby flex ostomy bag 2-piece open 570893229756497	Class IIa	NA	10000410282-PA-NA-DNK
SenSura Mio Baby flex ostomy baseplate 570893229760892	Class IIa	NA	10000410282-PA-NA-DNK
Alprep Pad 57089322853207G	Class Is	NA	10000410282-PA-NA-DNK
Assura/Alterna Post op ostomy bag 1-piece sterile 570893229762592	Class Is	NA	10000410282-PA-NA-DNK
SenSura Post op ostomy bag 1-piece sterile 57089322976228U	Class Is	NA	10000410282-PA-NA-DNK

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
SenSura drainable ostomy bag 1-piece open sterile 570893299814023VL	Class Is	NA	10000410282-PA-NA-DNK
SenSura Mio Post op ostomy bag 1-piece sterile 57089322976208Q	Class Is	NA	10000410282-PA-NA-DNK
Coloplast Drainage bag 1-piece open sterile 5708932117046058HZ	Class Is	NA	10000410282-PA-NA-DNK
EasiCath/SureCath Set urinary intermittent drainage catheter with integrated urine bag 57089322978199H	Class Is	NA	10000410282-PA-NA-DNK
EasiCath catheter urinary intermittent drainage catheter 57089322978169B	Class Is	NA	10000410282-PA-NA-DNK
Self-Cath urinary intermittent drainage catheter 570893229782296	Class Is	NA	10000410282-PA-NA-DNK
SpeediCath Control urinary intermittent drainage catheter 57089322978289J	Class Is	NA	10000410282-PA-NA-DNK
SpeediCath Standard urinary intermittent drainage catheter 57089322978269E	Class Is	NA	10000410282-PA-NA-DNK
SpeediCath Compact Eve urinary intermittent drainage catheter 57089322978349D	Class Is	NA	10000410282-PA-NA-DNK
SpeediCath Compact female/female plus urinary intermittent drainage catheter 57089322978339B	Class Is	NA	10000410282-PA-NA-DNK
SpeediCath Compact male urinary intermittent drainage catheter 570893229783197	Class Is	NA	10000410282-PA-NA-DNK
SpeediCath Compact Set female urinary intermittent drainage catheter with integrated urine bag 57089322978369H	Class Is	NA	10000410282-PA-NA-DNK
SpeediCath Compact Set Male urinary intermittent drainage catheter with integrated urine bag 57089322978359F	Class Is	NA	10000410282-PA-NA-DNK
SpeediCath Flex urinary	Class Is	NA	10000410282-PA-NA-

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
intermittent drainage catheter 57089322978379K			DNK
SpeediCath Flex Set urinary intermittent drainage catheter with integrated urine bag 5708932117288128LH	Class Is	NA	10000410282-PA-NA-DNK
SpeediCath Navi urinary intermittent drainage catheter 57089322978399P	Class Is	NA	10000410282-PA-NA-DNK
SpeediCath Soft urinary intermittent drainage catheter 570893261193271PW	Class Is	NA	10000410282-PA-NA-DNK
EasiCath Dilatation urinary intermittent dilatation catheter 57089322978179D	Class Is	NA	10000410282-PA-NA-DNK
EasiCath Luerlock urinary intermittent infusion and drainage catheter 57089322978189F	Class Is	NA	10000410282-PA-NA-DNK
Conveen Security+ bedside drainage bag sterile drainable sample port 57089322978919R	Class Is	NA	10000410282-PA-NA-DNK
Simpla Plus bedside drainage bag sterile drainable sample port 57089322978929T	Class Is	NA	10000410282-PA-NA-DNK
Simpla Profile bedside drainage bag sterile EtO drainable sample port 57089322978939V	Class Is	NA	10000410282-PA-NA-DNK
Simpla Profile bedside drainage bag sterile Irradiation drainable sample port 5708932117311270H4	Class Is	NA	10000410282-PA-NA-DNK
Simpla S4 bedside drainage bag sterile drainable sample port 5708932297896A3	Class Is	NA	10000410282-PA-NA-DNK
Simpla S5 bedside drainage bag sterile drainable sample port 5708932297897A5	Class Is	NA	10000410282-PA-NA-DNK
Conveen Standard combi bag sterile drainable 5708932297899A9	Class Is	NA	10000410282-PA-NA-DNK
Conveen Contour leg bag sterile drainable sample port	Class Is	NA	10000410282-PA-NA-DNK

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
57089322978709H			
Conveen Security+ leg bag sterile drainable 57089322978749R	Class Is	NA	10000410282-PA-NA-DNK
Conveen Security+ leg bag sterile drainable sample port 57089322978739P	Class Is	NA	10000410282-PA-NA-DNK
Freedom Triform leg bag sterile drainable sample port 57089322978769V	Class Is	NA	10000410282-PA-NA-DNK
Simpla Plus leg bag sterile drainable sample port 57089322978779X	Class Is	NA	10000410282-PA-NA-DNK
Simpla Plus Syphon leg bag sterile drainable sample port 57089322978789Z	Class Is	NA	10000410282-PA-NA-DNK
Simpla Profile leg bag sterile drainable sample port 57089322978819N	Class Is	NA	10000410282-PA-NA-DNK
Titan Inflatable Penile Prosthesis Family 570893291871755U9	Class IIb	Titan Inflatable Penile Prosthesis	10000410282-PA-NA-DNK
Titan Inflatable Penile Prosthesis Accessories 5708932110370449FT	Class IIb	Titan Inflatable Penile Prosthesis Accessories	10000410282-PA-NA-DNK
Genesis Malleable Penile Prosthesis 570893255573908T9	Class IIb	NA	10000410282-PA-NA-DNK
Virtue Male Sling System 570893255591814T7	Class III	NA	10000410282-PA-NA-DNK
Aris Introducers 570893255591823T8	Class IIa	NA	10000410282-PA-NA-DNK
Hydro X-Flow catheter silicone with hydrogel coating 57089326358899A	Class IIa	NA	10000410282-PA-NA-DNK
X-Flow prostatectomy catheter 570893263588898	Class IIa	NA	10000410282-PA-NA-DNK
Freudenberg introducer 570893263589697	Class Is	NA	10000410282-PA-NA-DNK
Connector for tubes	Class Is	NA	10000410282-PA-NA-DNK

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
57089326358608J			
Luer connector to syringe PVC 57089326358588X	Class Is	NA	10000410282-PA-NA-DNK
Luer lock connector for ureteric catheter to syringe polyamide 57089326358578V	Class Is	NA	10000410282-PA-NA-DNK
Tuohy borst adapter 57089326358568T	Class Is	NA	10000410282-PA-NA-DNK
Double loop ureteral stent set in polyamide 57089326283262 8RL	Class IIb Implantable	NA	10000410282-PA-NA-DNK
Double loop ureteral stent set in polyurethane 57089326283263 3RD	Class IIb Implantable	NA	10000410282-PA-NA-DNK
Detour subcutaneous ureteral bypass 57089326358478S	Class IIb implantable	NA	10000410282-PA-NA-DNK
Guidewire stainless steel without coating 57089326358468Q	Class IIa	NA	10000410282-PA-NA-DNK
Stainless steel PTFE coated guidewire 57089326358458N	Class IIa	NA	10000410282-PA-NA-DNK
Percutaneous nephrostomy guidewire 57089326358448L	Class IIa	NA	10000410282-PA-NA-DNK
Luer connector for urine bag 57089326358648S	Class Is	NA	10000410282-PA-NA-DNK
Vortek J percutaneous nephrostomy catheter 57089326358628N	Class IIb	NA	10000410282-PA-NA-DNK
Vortek malecot percutaneous nephrostomy catheter 57089326283258 2RM	Class IIb	NA	10000410282-PA-NA-DNK
Balloon nephrostomy catheter short term (Silicone nephrostomy balloon catheters) 57089326358498W	Class IIb	NA	10000410282-PA-NA-DNK
Percutaneous nephrostomy dilator 57089326358518H	Class IIa	NA	10000410282-PA-NA-DNK
Percutaneous puncture needle 57089326358508F	Class IIa	NA	10000410282-PA-NA-DNK
Direct puncture set 57089326358538M	Class IIb	NA	10000410282-PA-NA-DNK

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
Percutaneous nephrostomy set with simple loop vortek catheter 570893262832546RH	Class IIb	NA	10000410282-PA-NA-DNK
Dormia No-Tip / N-Stone 570893263586994	Class IIa	NA	10000410282-PA-NA-DNK
Biosoft duo double loop ureteral stent 57089326358348H	Class IIb implantable	NA	10000410282-PA-NA-DNK
Biosoft duo multilength hydro-coated ureteral stent 570893262832542R9	Class IIb implantable	NA	10000410282-PA-NA-DNK
Double loop in rigid polyurethane 57089326358278L	Class IIb implantable	NA	10000410282-PA-NA-DNK
Double loop in soft polyurethane 57089326358268J	Class IIb implantable	NA	10000410282-PA-NA-DNK
Double loop ureteral stent in silicone 57089326358298Q	Class IIb implantable	NA	10000410282-PA-NA-DNK
Double loop ureteral stent silicone hydrogel 57089326358328D	Class IIb implantable	NA	10000410282-PA-NA-DNK
Double loop ureteral stent in silicone with partial reinforcement 570893263583089	Class IIb implantable	NA	10000410282-PA-NA-DNK
Double loop ureteral stent in silicone with total reinforcement 57089326358318B	Class IIb implantable	NA	10000410282-PA-NA-DNK
Single loop ureteral stent 57089326358228A	Class IIb	NA	10000410282-PA-NA-DNK
Tumor Stent double loop ureteral stent 57089326358258G	Class IIb implantable	NA	10000410282-PA-NA-DNK
Vortek double loop ureteral stent 57089326358248E	Class IIb implantable	NA	10000410282-PA-NA-DNK
Vortek hydro-coated double loop ureteral stent with hydrogel coating 57089326358238C	Class IIb implantable	NA	10000410282-PA-NA-DNK
Non steerable pusher 570893262832532R6	Class IIa	NA	10000410282-PA-NA-DNK

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
Non steerable radiopaque pusher 570893262832531R4	Class IIa	NA	10000410282-PA-NA-DNK
Steerable pusher 570893262832522R3	Class IIa	NA	10000410282-PA-NA-DNK
Ureteric drainage catheter in neoplex 57089326358368M	Class IIa	NA	10000410282-PA-NA-DNK
Ureteric drainage catheter in polyamide 57089326358378P	Class IIa	NA	10000410282-PA-NA-DNK
Floppy tip hydro-coated ureteric catheter 57089326358408C	Class IIa	NA	10000410282-PA-NA-DNK
Ureteric interventional catheter 57089326358398T	Class IIa	NA	10000410282-PA-NA-DNK
Ureteric catheter for retrograde uretero-pyelography 57089326358388R	Class Is	Ureteric catheter for retrograde uretero-pyelography	10000410282-PA-NA-DNK
Retrace ureteral access sheath 57089326358418E	Class IIa	NA	10000410282-PA-NA-DNK
Ureteral dilator 57089326358428G	Class Is	NA	10000410282-PA-NA-DNK
Short term enterocystoplasty catheter 57089326358088G	Class IIa	NA	10000410282-PA-NA-DNK
Short term uretero-sigmoidostomy catheter 57089326358078E	Class IIa	NA	10000410282-PA-NA-DNK
Single loop ureterostomy catheter 570893263581083	Class IIb	NA	10000410282-PA-NA-DNK
Ureterostomy catheter 57089326358098J	Class IIb	NA	10000410282-PA-NA-DNK
Elefant suction-irrigation device 570893263590085	Class IIa	NA	10000410282-PA-NA-DNK
Escat transcystic drains in PVC 57089326359058F	Class IIa	NA	10000410282-PA-NA-DNK
Pedinielli transcystic drains in PVC 57089326359048D	Class IIa	NA	10000410282-PA-NA-DNK
Coeliodrain for cholangiography 570893263590289	Class IIa	NA	10000410282-PA-NA-DNK
Delbet drains 57089326359078K	Class IIa	NA	10000410282-PA-NA-DNK

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
Multitubular drain silicone 57089326359068H	Class IIa	NA	10000410282-PA-NA-DNK
Tubular drains silicone 570893262838040RN	Class IIa	NA	10000410282-PA-NA-DNK
Multi-perforated tubular drain silicone radiopaque 57089326359098P	Class IIa	NA	10000410282-PA-NA-DNK
Bonee needle for bladder injection 570893263588694	Class IIa	NA	10000410282-PA-NA-DNK
Neoplex catheters without balloon 570893263587793	Class IIa	NA	10000410282-PA-NA-DNK
Catheter valve 57089326358768Z	Class Is	NA	10000410282-PA-NA-DNK
Folysil silicone catheter 57089326358748V	Class IIb	NA	10000410282-PA-NA-DNK
Folysil silicone catheter - Long-term 57089326358758X	Class IIb implantable	NA	10000410282-PA-NA-DNK
Cystodrain supra-pubic drainage set with silicone J tip catheter 57089326358808Q	Class IIb	NA	10000410282-PA-NA-DNK
Cystodrain supra-pubic puncture set with polyurethane J tip catheter 57089326358818S	Class IIb	NA	10000410282-PA-NA-DNK
Cystodrain integral set for supra-pubic drainage 57089326358828U	Class IIb	NA	10000410282-PA-NA-DNK
Supraflow supra-pubic drainage set with silicone balloon catheter 570893263588592	Class IIb	NA	10000410282-PA-NA-DNK
Uristil suprapubic drainage set in silicone 57089326358838W	Class IIb	NA	10000410282-PA-NA-DNK
Bougie neoplex for routine urethral dilation 570893263587997	Class Is	NA	10000410282-PA-NA-DNK
Filiform bougie neoplex 570893263587895	Class Is	NA	10000410282-PA-NA-DNK

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: (Delete if Not Applicable)

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
Furlow Insertion Tool 570893255573897TV	Class Ir	Furlow Insertion Tool	N/A - Device did not require a Notified Body certificate under Directives
Rossello Dilator Set 570893255573898TX	Class Ir	NA	N/A - Device did not require a Notified Body certificate under Directives
Brooks Dilator Set 5708932121570220GP	Class Ir	Brooks Dilator Set	N/A - Device did not require a Notified Body certificate under Directives
Brava Paste 57089322976729B	Class IIa	NA	N/A - Device did not require a Notified Body certificate under Directives
Coloplast Paste 570893229767199	Class IIa	NA	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/09/20	C627818	Initial issue
2024/07/30	C627818	Rev. 1: - Added Biatain Superabsorber and removed Biatain Super Adhesive dressing and Biatain Super Non-Adhesive dressing. - Moved three devices to table 2.
2024/09/02	C627818	Rev. 2: Addition of “Brava Paste” and “Coloplast paste”

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