Confirmation Letter Regarding Amending Regulation (EU) 2023/607

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
	PSE200130012078	+49 40 840521-119	+49 40 840521-198	2024-03-08	1 of 8

B.Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Germany

Contents

TÜV SÜD Product Service GmbH
Receipt of formal application

Reference: MDR-BBMAG-2024-01-001 (G10)
PSE200130012078

To whom it may concern,

Confirmation of the status of a formal application in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received **a formal application** in accordance with Section 4.3, first subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000000201

The devices covered by the formal application mentioned above are identified in the Table below.

Please note that this letter only confirms the status of the formal application.
To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
27-03-2024

Confirmation Letter Regarding Amending Regulation (EU) 2023/607

TÜV SÜD Product Service GmbH
Medical and Health Services

Ulrike Martin

Ulrike Martin (28. März 2024 09:37 GMT+1)

Ulrike Martin
Conformity Assessment Responsible (CARE)

Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

Device name (under MDR application)
Perfusor Compact plus
Infusomat Compact plus
OnlineSuite
Spaceplus Perfusor
Spaceplus Infusomat
Infusomat Compact plus P
Sangofix® Air
Omnifix® Lock
Omnican fine
Drainobag® 600 V
Drug Library Manager Spaceplus
Drug Library Manager Spaceplus
GLYCINE 1,5 % B. BRAUN
NaCl 0,9 % B. BRAUN
NaCl 0,9 % B. BRAUN
Vitulia
NaCl 0,9 % B. BRAUN
NaCl 0,9 % B. BRAUN
RINGER B. BRAUN
RINGER B. BRAUN
RINGER B. BRAUN
RINGER B. BRAUN
Aqua B. Braun
Aqua B. Braun
Aqua B. Braun
Perifix Catheter Connector
Perifix Catheter Connector
Perifix Catheter Connector NRFit
Perifix Catheter Connector NRFit
Infusomat® Space
Infusomat® Space P

Confirmation Letter Regarding Amending Regulation (EU) 2023/607

Device name (under MDR application)

Perfusor® Space
Enteroport plus
Infusomat® Plus Line SafeSet
Infusomat® Plus Line
Cyto-Set® Infusomat® Space
Cyto-Set® Line
Cyto-Set® Mix
Stimuplex® A
Easypump® II LT 60-12
Easypump® II LT 500-12.5
Easypump® II LT 80-16
Easypump® II LT 125-25
Easypump® II LT 270-27
Easypump® II LT 60-30
Easypump® II LT 120-30
Easypump® II LT 400-40
Easypump® II LT 100-50
Easypump® II LT 270-54
Easypump® II LT 400-80
Easypump® II LT 270-68
Easypump® II LT 400-100
Easypump® II LT 270-135
Easypump® II ST 100-0,5
Easypump® II ST 250-0,5
Easypump® II ST 50-1
Easypump® II ST 100-1
Easypump® II ST 250-1
Easypump® II ST 250-1,5
Easypump® II ST 400-2
Easypump® II ST 500-2
Easypump® II ST 100-2
Easypump® II ST 400-4
Spinal Introducer
Contiplex® S 360
Contiplex® S Ultra 360®
Perifix Filter
Perifix Filter NRFit
Contiplex® S Ultra 360® NRFit®
Contiplex® Tuohy Ultra 360®
Discofix®

Confirmation Letter Regarding Amending Regulation (EU) 2023/607

Device name (under MDR application)

Nutritub® ENFit® intestinal
Nutritub® Gastral Basic ENFit®
Infusomat® Space Line
IN-Stopper
Combi-Stopper
Combifix® Adapter
Original Perfusor® Lines Type ENFitTM
Pleurofix® No. 1
Pleurofix® No. 2
Seldinger Introducer Needle
Injekt® 40 Duo
Introcan Safety® 3
Mini-Redovac® 50 K 6
Mini-Redovac® 50 K 8
Infusomat® Space Line
Infusomat® Space Line SafeSet
Infusomat® Space Line
Infusomat® Plus Line
Enteroport® ENFit® Set
Double Spike Adaptor
Extension Line, Type: Alargadera
In-line injection tubing
LS-3 Connector
LS-2 Connector
LS-4 Connector
LS-5 Connector
Original-Kucher-extension tubing
LS-2 Connector
ProSet Cyto-Set®
ProSet Cyto-Set® Infusomat® Space
ProSet Cyto-Set® Mix
ProSet Cyto-Set® Line
ProSet Cyto-Set® Pump Adapter
Cyto-Set® Pump Adapter
Dosifix®
Dosifix®
Heidelberger Extension Tubing
Extension Line, Type: Heidelberger
Introcan® Certo
Introcan®

Confirmation Letter Regarding Amending Regulation (EU) 2023/607

Device name (under MDR application)

Introcan®-W Certo
Introcan®-W
Introcan®-W With In-stopper
Discofix® C Safeflow
Sterifix®
Sterifix® Neonat
Intrapur®
Intrapur® Lipid
Intrapur®-Neonat Lipid
Discofix® C
Pleuracan®
Pleuracan® B
Pleuracan® Back-Check Valve
Drainobag® Lock 600
Discofix® C
Heidelberger Extension Tubing
Introcan Safety®
Introcan Safety®-W
ProSet Intrapur®
ProSet Sterifix® Neonat
ProSet Discofix® C
Vasofix® Braunüle®
Vasofix® Certo
Extension Line
ProSet Extension Line
ProSet Spiral Line
Vasofix® Safety
Infusomat®plus Line SafeSet
Infusomat®plus Line SafeSet
Infusomat® Space Line SafeSet
Infusomat® Space Line SafeSet
Intrafix® Primeline
Intrafix® SafeSet
Drainobag® Basse Pression
Drainobag® Lock 300
Drainobag® 150
Drainobag® Lock 150
Drainobag® Bayonet 400
Drainobag® 600 V
Drainobag® Lock 600 V

Device name (under MDR application)

Drainobag® Basse Pression TL
Drainobag® 300 V
Drainobag® Lock 300 V
Drainobag® 150 V
Drainobag® 150 VL
Drainobag® Lock 150 V
Drainobag® Lock 150 VL
Drainobag® 400 V
Drainobag® Bayonet 400 V
Drainobag® Lock 600 K 10
Drainobag® Lock 600 K 12
Intrafix® SafeSet
ProSet Intrafix® Primeline
ProSet Intrafix® SafeSet
Intrafix® Primeline
Intrafix® SafeSet
ProSet Intrafix®
Intrafix® Primeline
SafeSet
Infusomat® Plus Line
Infusomat® Plus Line SafeSet
Infusomat® Space Line
Infusomat® Space Line
Infusomat® Plus Line
Omnican® fine
Infusomat® Plus Line SafeSet
Original Perfusor® Line
Infusomat® Plus Line
ProSet Infusomat® Space Line
Infusomat® Space Line
ProSet Original Perfusor® Line
Original Perfusor® Line
ProSet Infusomat® Space Line
Infusomat® Space Line SafeSet
Infusomat® Space Line
Sangofix®
Sangofix® Air
Original Perfusor® Line
Infuvalve®
Combi-Stopper

Device name (under MDR application)

Safeflow Extension Set
Safeflow
Safeflow Extension Set
Omnican® fine
Omnican® 50
Omnican® 100
Omnican® 20
Omnican® F
IBSA FSH/LH
Serofine™ needle
B. Braun Pen Needle
Pencylcap™
Pen Needle B. Braun F-Pen DS
Drainobag® Lock 600 K 14
Drainobag® Lock 600 K 16
Drainobag® 150 K 6
Drainobag® 150 K 8
Omnifix® 40 Duo
Omnifix® Luer Duo
Omnifix® Luer Lock Solo
Omnifix® Luer Lock Solo
Sterican® Safety Needle
Sterican®
Injekt®-H Luer Duo
Injekt® Luer Duo
Injekt®-F Luer Duo
Sterican® Safety Needle
Contiplex® D
Contiplex® D
Contiplex® C
Ultraplex® 360
Ultraplex® 360 NRFit®
Stimuplex® D
Stimuplex® D NRFit®
Stimuplex® Ultra 360®
Stimuplex® 360®
Stimuplex® Ultra 360® NRFit®
Omnifix® Lock
Original Perfusor® Syringe 20 ml
Original Perfusor® Syringe 20 ml

Confirmation Letter Regarding Amending Regulation (EU) 2023/607

Device name (under MDR application)

Original Perfusor® Syringe 50 ml
Original Perfusor® Syringe 50 ml
Original Perfusor® Syringe 50 ml
Original Perfusor® Syringe 50 ml
Original Perfusor® Syringe 50 ml
Cystofix®
Cystofix®
Cystofix SG
Cystofix
Vasco® OP Powdered
Vasco® OP Sensitive
Vasco® OP Underglove
Vasco® OP eco
Vasco® OP Grip
Vasco® OP Free
Drainobag® Connection Tube Bayonet