

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	CA-MI S.r.l.
Manufacturer address and contact details	Via Ugo La Malfa 13 – Frazione Pilastro 43013 Langhirano (PR) Italy e-mail: m.saccani@ca-mi.it
Single Registration Number (SRN) (if available)	IT-MF-000020076

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	TÜV SÜD PRODUCT SERVICE GMBH
Notified body number (if applicable)	0123
Directive Certificate number(s) to which this confirmation is made (if applicable)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26/05/2024
End date of extended validity/transition period	31/12/2028

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

- Expired *before* 20 March 2023:
 - Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
 - A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
 - A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

Choose one applicable statement:

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: CA-MI S.r.l.
Location & Date: Langhirano (PR) Italy, 04.04.2024
Signature, Print Name, Title: Manuel Saccani (Quality Assurance / Person Responsible for Regulatory Compliance)

CA-MI S.r.l.
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Contact Details (at least email) m.saccani@ca-mi.it / tecnico@ca-mi.it

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices

Identification of the device(s) ³ (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
COMPACT (REF RE 300200)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE SERVICE GMBH (0123)	31.12.2028	Not Applicable
COMPACT (REF RE 300200/02)	Families: Aerosol Therapy Equipment Budi: 8054610910Z121590023V					
MINIMAX (REF RE 300250)						
ZEFIRO (REF RE 300250/03)						
SIMPLE (REF RE 300250/04)						
MINIMAX 2 (REF RE 300250/05)						
MINIMAX (REF RE 300250/06)						
MINIMAX COMBY (REF RE 300250/08)						
SEA FAIR (REF RE 300250/11)						
GEM (REF RE 300250/10)						
PRONTEX FLOW (REF RE 300230)						
FARMASOL (REF RE 300230/01)						
ME 100 (REF RE 300230/02)						
EVERCHECK NB200 (REF RE 300240/03)						
KUBYNEB (REF RE 300240)						
KUBYNEB (REF RE 300240/01)						
EVERCHECK NB100 (REF RE 300240/02)						
AEROPLUS (REF RE 300240/03)						
ME 110 (REF RE 300240/04)						
EOLO (REF RE 300400)						
EOLO (REF RE 300400/05)						
FLO-EOLO (REF RE 300400/15)						
EOLO (REF RE 300400/07)						
EOLO (REF RE 300400/12)						
EOLO (REF RE 300400/16)						

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Identification of the device(s) ³ (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
PRONTEX WIND (REF RE 300430)						
EVOLUTION (REF RE 300450)						
MOBILE (REF RE 300700)						
MOBILE (REF RE 300700/04)						
CLINEB (REF RE 300550/03)						
CLINEB BASIC (REF RE 300551/03)						
AIR THERAPY (REF RE 300550/02)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
CLINEB PRO (REF RE 300560)	Families: Aerosol Therapy Equipment Budi: 8054610910Z121590023V					
MIKO (REF RE 300600/03)						
MIKO BASIC (REF RE 300600/12)						
BABY MIKO (REF RE 300600/08)						
MIKO (REF RE 300600/11)						
AIR PLUS 2000 (REF RE 300600/15)						
AEROPHARMA (REF RE 300600/17)						
MIKO (REF RE 300600/18)						
KIWI PLUS (REF RE 300911)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
ONE PLUS (REF RE 300912)	Families: Aerosol Therapy Equipment Budi: 8054610910Z12159002MHPP					
ONE PRO (REF RE 300912/01)						
AIREASY ON (REF RE 300912/02)						
HI-FLO KIT (REF RE 300300/09)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
HI-FLO KIT (REF RE 300300)	Families: Kits For Aerosol Therapy Budi: 8054610910R060101T3					
HI-FLO KIT (REF RE 300300/01)						
HI-FLO KIT (REF RE 300300/02)						
HI-FLO KIT (REF RE 300300/05)						
HI-FLO KIT (REF RE 300300/06)						
HI-FLO KIT (REF RE 300300/12)						
SET ACCESSORI AEROSOLTERAPIA (REF RE 300300/13)						
HI-FLO KIT (REF RE 300300/15)						
PRONTEX AMPOLLA AEROSOL RAPID 2 (REF 01200)						

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HI-4 KIT (REF RE 300350)						
HI-4 + BOCCHERUOLA (REF RE 300350/01)						
NASO-FREE (REF DN 100100)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
RHINO CARE (REF DN 100100/02)	Families: Kits For Aerosol Therapy					
NASO-FREE (REF DN 100100/03)	Budi: 8054610910R06992S					
NEW VAPINAL (REF RE 420000)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
INALFAST (REF RE 420000/01)	Families: Thermal Water Inhaler					
NEW VAPINAL (REF RE 320000)	Budi: 8054610910Z121590002IPT					
TERMALVAP (REF RE 320000/03)						
INALPHARMA (REF RE 320000/10)						
NEW ASPIRET (REF RE 310001)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASPIRET (REF RE 310001/01)	Families: Surgical Suction Equipment					
NEW ASPIRET (REF RE 310002)	Budi: 8054610910Z120105WL					
NEW ASPIRET (REF RE 310002/01)						
NEW ASPIRET (REF RE 310001/07)						
NEW ASPIRET (REF RE 310001/13)						
NEW ASKIR 15 (REF RE 310001/15)						
NEW ASKIR 15 (REF RE 310001/16)						
NEW ASKIR 15 (REF RE 310001/17)						
NEW ASKIR 15 (REF RE 310001/18)						
KATASPIR 20 ECO (REF RE 310001/06)						
LIFEMED 15 (REF RE 310001/14)						
NEW ASPIRET (REF RE 310001/19)						
NEW ASKIR 20 (REF RE 310100/12)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASKIR 20 (REF RE 310100/13)	Families: Surgical Suction Equipment					
NEW ASKIR 20 (REF RE 310100/64)	Budi: 8054610910Z120105WL					
NEW ASKIR 20 (REF RE 310100/70)						
NEW ASKIR 20 (REF RE 310101/12)						
NEW ASKIR 20 (REF RE 310101/13)						
KATASPIR 20 (REF RE 310100/46)						

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LIFEMED 20 (REF RE 310100/58)						
NEW ASKIR (REF RE 310100/72)						
TECNO 15 (REF RE 310100/66)						
TECNO 15 (REF RE 310100/67)						
NEW ASKIR 30 (REF RE 310100/02)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASKIR 30 (REF RE 310100/03)	Families: Surgical Suction Equipment Budi: 8054610910Z120105WL					
NEW ASKIR 30 (REF RE 310101/02)						
NEW ASKIR 30 (REF RE 310100/53)						
NEW ASKIR 30 (REF RE 310100/18)						
NEW ASKIR 30 (REF RE 310100/30)						
NEW ASKIR 30 (REF RE 310100/40)						
NEW ASKIR 30 (REF RE 310100/63)						
NEW ASKIR 30 (REF RE 310100/74)						
NEW ASKIR (REF RE 310100/71)						
KATASPIR 30 (REF RE 310100/21)						
LIFEMED 40 (REF RE 310100/57)						
TECNO 25 (REF RE 310100/68)						
TECNO 25 (REF RE 310100/69)						
NEW ASKIR 30 PROXIMITY (REF RE 310100/55)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASKIR 30 PROXIMITY (REF RE 310100/56)	Families: Surgical Suction Equipment Budi: 8054610910Z120105WL					
NEW ASKIR 30 PROXIMITY (REF RE 310100/62)						
NEW ASKIR 30 PROXIMITY (REF RE 310100/75)						
NEW ASKIR 30 PROXIMITY (REF RE 310100/76)						
NEW ASKIR 30 PROXIMITY (REF RE 310100/77)						
NEW ASKIR 30 PROXIMITY (REF RE 310100/78)						
NEW ASKIR 30 PROXIMITY (REF RE 310100/79)						

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NEW ASKIR 30 PROXIMITY (REF RE 310101/03)												
NEW ASKIR 30 PROXIMITY (REF RE 310101/04)												
NEW ASKIR 30 PROXIMITY (REF RE 310101/07)												
NEW ASKIR 30 PROXIMITY (REF RE 310101/089)												
AS-100 (REF RE 410100)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable						
AS-100 (REF RE 410100/04)	Families: Surgical Suction Equipment Budi: 8054610910Z120105WL											
ASPIMED 2.3 (REF RE 410100/26)												
ACEEVAC SUC 81025 (REF RE 410100/01)												
AS-200 (REF RE 410120)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable						
AS-200 (REF RE 4101120/01)	Families: Surgical Suction Equipment Budi: 8054610910Z120105WL											
ASPIMED 2.2 (REF RE 410120/25)												
NEW ASKIR 230/12V BR (REF RE 310211)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable						
NEW ASKIR 230/12V BR (REF RE 310211/01)	Families: Surgical Suction Equipment Budi: 8054610910Z120105WL											
NEW ASKIR 230/12V BR (REF RE 310211/03)												
NEW ASKIR 230/12V BR (REF RE 310211/04)												
NEW ASKIR 230/12V BR (REF RE 310211/06)												
NEW ASKIR 230/12V BR (REF RE 310211/11)												
NEW ASKIR 230/12V BR (REF RE 310211/12)												
NEW ASKIR 230/12V BR (REF RE 310211/13)												
NEW ASKIR 230/12V BR (REF RE 310211/14)												
NEW ASKIR 230/12V BR (REF RE 310211/15)												
NEW ASKIR 230/12V BR (REF RE 310211/10)												
KATASPIR 230/12V BR (REF RE 310211/02)												
TECNO 16B (111-A) (REF RE 310211/08)												
TECNO 16B (114-A) (REF RE 310211/09)												
AS-12VBR (REF RE 410200)							MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
ASPIMED 2.5 (REF RE 410200/02)							Families: Surgical Suction Equipment					

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	Budi: 8054610910Z120105WL					
ASKIR 36BR (REF RE 410200/03)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
ASKIR 36BR (REF RE 410200/09)	Families: Surgical Suction Equipment Budi: 8054610910Z120105WL					
ASKIR 36BR (REF RE 410200/12)						
ASKIR 36BR (REF RE 410200/13)						
ASKIR 36BR (REF RE 410200/14)						
ASKIR 36BR (REF RE 410200/10)						
ASKIR 36BR (REF RE 410201)						
ASKIR 36BR (REF RE 410201/01)						
ASKIR 36BR (REF RE 410200/04)						
NEW ASKIR 36BR (REF RE 410200/05)						
NEW ASKIR 36BR (REF RE 410200/06)						
NEW ASKIR (REF RE 410200/11)						
KATASPIR 36BR (REF RE 410200/07)						
AS-36BR (REF RE 410210/01)						
AS-36BR (REF RE 410210/03)	Families: Surgical Suction Equipment Budi: 8054610910Z120105WL					
AS-36BR (REF RE 410210/04)						
CEEVAC SUC 81030 (REF RE 410210/02)						
NEW ASKIR 36 LI-ION (REF RE 410205)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW ASKIR 36 LI-ION (REF RE 410205/01)	Families: Surgical Suction Equipment Budi: 8054610910Z120105WL					
NEW ASKIR 36 LI-ION (REF RE 410205/02)						
NEW ASKIR 36 LI-ION (REF RE 410205/03)						
NEW ASKIR 36 LI-ION (REF RE 410205/04)						
NEW ASKIR 36 LI-ION (REF RE 410205/05)						
NEW ASKIR 36 LI-ION (REF RE 410205/06)						
NEW ASKIR 36 LI-ION (REF RE 410205/07)						
NEW ASKIR 36 LI-ION (REF RE 410205/08)						
NEW ASKIR 36 LI-ION (REF RE 410205/09)						
NEW ASKIR 36 LI-ION (REF RE 410205/10)						
NEW ASKIR 36 LI-ION (REF RE 410205/11)						

Identification of the device(s) ³ (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)						
NEW ASKIR 118 (REF RE 410150)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable						
NEW ASKIR 118 (REF RE 410150/01)	Families: Surgical Suction Equipment Budi: 8054610910Z120105WL											
NEW ASKIR 118 (REF RE 410150/02)												
NEW ASKIR 118 (REF RE 410150/05)												
NEW ASKIR 118 (REF RE 410151)												
NEW ASKIR 118 (REF RE 410151/01)												
NEW ASKIR 118 (REF RE 410150/02)												
NEW ASKIR 118 (REF RE 410151/05)												
NEW ASKIR 30 12V (REF RE 310150/02)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable						
NEW ASKIR 30 12V (REF RE 310150/05)	Families: Surgical Suction Equipment Budi: 8054610910Z120105WL											
NEW ASKIR 118 BASIC (REF RE 410171)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable						
NEW ASKIR 118 BASIC (REF RE 410171/01)	Families: Surgical Suction Equipment Budi: 8054610910Z120105WL											
NEW ASKIR 118 BASIC (REF RE 410171/02)												
NEW ASKIR 118 BASIC (REF RE 410171/03)												
NEW ASKIR 118 BASIC (REF RE 410171/04)												
NEW ASKIR 118 BASIC (REF RE 410171/05)												
NEW ASKIR 118 BASIC (REF RE 410171/06)												
NEW ASKIR 118 BASIC (REF RE 410171/07)												
NEW ASKIR 118 BASIC (REF RE 410170)												
NEW ASKIR 118 BASIC (REF RE 410170/01)												
NEW ASKIR 118 BASIC (REF RE 410170/02)												
NEW ASKIR 118 BASIC (REF RE 410170/03)												
ASKIR C30 (REF RE 410250)							MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
ASKIR C30 (REF RE 410250/01)							Families: Surgical Suction Equipment Budi: 805461910Z120105PXP					
ASKIR C30 (REF RE 410250/10)												
ASKIR C30 (REF RE 410250/14)												
ASKIR C30 (REF RE 410250/15)												
ASKIR C30 (REF RE 410250/16)												
ASKIR C30 BR	MDD 93/42/EEC Certificate	26.05.2024	TÜV SÜD	TÜV SÜD	31.12.2028	Not Applicable						

Identification of the device(s) ³ (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
(REF RE 410251) ASKIR C30 BR (REF RE 410251/01) ASKIR C30 BR (REF RE 410251/03) ASKIR C30 BR (REF RE 410251/04) ASKIR C30 BR (REF RE 410251/05) ASKIR C30 BR (REF RE 410251/06)	No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461910Z120105PXP		PRODUCT SERVICE GMBH (0123)	PRODUCT SERVICE GMBH (0123)		
NEW HOSPIVAC BR (REF RE 410400) NEW HOSPIVAC BR (REF RE 410400/01) NEW HOSPIVAC BR (REF RE 410400/02) NEW HOSPIVAC BR (REF RE 410400/03)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461910Z120105PXP	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW HOSPIVAC 400 (REF RE 410350) NEW HOSPIVAC 400 (REF RE 410350/01) NEW HOSPIVAC 400 (REF RE 410350/03) NEW HOSPIVAC 400 (REF RE 410350/05) NEW HOSPIVAC 400 (REF RE 410350/08) NEW HOSPIVAC 400 (REF RE 410350/09) NEW HOSPIVAC 400 (REF RE 410350/10) NEW HOSPIVAC 400 (REF RE 410350/11) NEW HOSPIVAC 400 (REF RE 410350/18) NEW HOSPIVAC 400 (REF RE 410350/25) NEW HOSPIVAC 400 (REF RE 410350/27) NEW HOSPIVAC 400 (REF RE 410350/28) NEW HOSPIVAC 400 (REF RE 410350/36) NEW HOSPIVAC 400 (REF RE 410350/37) NEW HOSPIVAC 400 (REF RE 410350/38) NEW HOSPIVAC 400 (REF RE 410350/39) NEW HOSPIVAC 400 (REF RE 410350/30) NEW HOSPIVAC 400 (REF RE 410350/32) NEW HOSPIVAC 400 (REF RE 410350/33) NEW HOSPIVAC 400 (REF RE 410350/35) NEW HOSPIVAC 400	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461910Z120105PXP	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable

Identification of the device(s)³ (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
(REF RE 410350/40)						
NEW HOSPIVAC 400 (REF RE 410350/43)						
NEW HOSPIVAC 400 (REF RE 410350/44)						
NEW HOSPIVAC 400 (REF RE 410350/45)						
NEW HOSPIVAC 400 (REF RE 410350/46)						
NEW HOSPIVAC 400 (REF RE 410350/47)						
NEW HOSPIVAC 400 (REF RE 410350/48)						
NEW HOSPIVAC 400 (REF RE 410350/57)						
NEW HOSPIVAC 400 (REF RE 410350/58)						
NEW HOSPIVAC 400 (REF RE 410350/59)						
NEW HOSPIVAC 400 (REF RE 410350/60)						
NEW HOSPIVAC 400 (REF RE 410350/61)						
NEW HOSPIVAC 400 (REF RE 410350/62)						
NEW HOSPIVAC 400 (REF RE 410350/65)						
NEW HOSPIVAC 400 (REF RE 410350/66)						
NEW HOSPIVAC 400 (REF RE 410350/67)						
NEW HOSPIVAC 400 (REF RE 410350/62)						
NEW HOSPIVAC 400 (REF RE 410350/68)						
NEW HOSPIVAC 400 (REF RE 410350/69)						
NEW HOSPIVAC 400 (REF RE 410350/70)						
NEW HOSPIVAC 400 (REF RE 410350/71)						
NEW HOSPIVAC 400 (REF RE 410350/72)						
LIFEMED 90 (REF RE 410350/13)						
KYRI DSS (REF RE 410350/41)						
TECNO 90 (REF RE 410350/55)						
TECNO 90 (REF RE 410350/56)						
TECNO 90 (REF RE 410350/49)						
KATASPIR PRO (REF RE 410350/50)						
KATASPIR PRO (REF RE 410350/51)						
HiFlo2 – SUC 84602 (REF RE 410350/63)						
HiFlo2 Max						

Identification of the device(s) ³ (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
SUC 84604 (REF RE 410350/64)						
NEW HOSPIVAC 350 (REF RE 410356)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW HOSPIVAC 350 (REF RE 410356/01)	Families: Surgical Suction Equipment Budi: 805461910Z120105PXP					
NEW HOSPIVAC 350 (REF RE 410356/02)						
NEW HOSPIVAC 350 (REF RE 410356/05)						
NEW HOSPIVAC 350 (REF RE 410356/06)						
NEW HOSPIVAC 350 (REF RE 410356/07)						
NEW HOSPIVAC 350 (REF RE 410356/08)						
NEW HOSPIVAC 350 (REF RE 410356/09)						
NEW HOSPIVAC 350 (REF RE 410356/27)						
NEW HOSPIVAC 350 (REF RE 410356/28)						
NEW HOSPIVAC 350 (REF RE 410356/29)						
NEW HOSPIVAC 350 (REF RE 410356/30)						
NEW HOSPIVAC 350 (REF RE 410356/39)						
NEW HOSPIVAC 350 (REF RE 410356/40)						
NEW HOSPIVAC 350 (REF RE 410356/41)						
NEW HOSPIVAC 350 (REF RE 410356/38)						
NEW HOSPIVAC 350 (REF RE 410356/43)						
NEW HOSPIVAC 350 (REF RE 410356/54)						
NEW HOSPIVAC 350 (REF RE 410356/55)						
NEW HOSPIVAC 350 (REF RE 410356/56)						
NEW HOSPIVAC 350 (REF RE 410356/58)						
TECNO 40 (REF RE 410356/57)						
NEW HOSPIVAC 350 (REF RE 410350/25)						
NEW HOSPIVAC 350 (REF RE 410350/26)						
NEW HOSPIVAC 350 (REF RE 410350/32)						
NEW HOSPIVAC 350 (REF RE 410350/36)						
NEW HOSPIVAC 350 (REF RE 410350/37)						
NEW HOSPIVAC 350 (REF RE 410350/34)						
NEW HOSPIVAC 350 (REF RE 410350/51)						

Identification of the device(s) ³ (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
NEW HOSPIVAC 350 (REF RE 410350/52)						
NEW HOSPIVAC 350 (REF RE 410350/53)						
NEW HOSPIVAC 350 (REF RE 410350/44)						
NEW HOSPIVAC 350 (REF RE 410350/46)						
NEW HOSPIVAC 350 (REF RE 410350/47)						
NEW HOSPIVAC 350 (REF RE 410350/48)						
NEW HOSPIVAC 350 (REF RE 410350/49)						
NEW HOSPIVAC 350 (REF RE 410350/50)						
NEW HOSPIVAC 350 (REF RE 410350/51)						
NEW HOSPIVAC 350 (REF RE 410350/52)						
NEW HOSPIVAC 350 (REF RE 410350/53)						
NEW HOSPIVAC 350 (REF RE 410350/59)						
NEW HOSPIVAC 350 (REF RE 410350/60)						
NEW HOSPIVAC 350 (REF RE 410350/61)						
NEW HOSPIVAC 350 (REF RE 410350/62)						
NEW HOSPIVAC 350 (REF RE 410350/63)						
NEW HOSPIVAC 350 (REF RE 410350/64)						
NEW HOSPIVAC 350 (REF RE 410350/65)						
NEW HOSPIVAC 350 (REF RE 410350/66)						
NEW HOSPIVAC 350 (REF RE 410350/67)						
NEW HOSPIVAC 350 (REF RE 410350/68)						
NEW HOSPIVAC 350 (REF RE 410350/69)						
NEW HOSPIVAC 350 (REF RE 410350/70)						
NEW HOSPIVAC 350 (REF RE 410350/71)						
NEW HOSPIVAC 350 (REF RE 410350/72)						
NEW EMIVAC (REF RE 310300)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Surgical Suction Equipment Budi: 805461910Z120105MXH	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
NEW MAMILAT (REF DC 620010)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01	26.05.2024	TÜV SÜD PRODUCT SERVICE	TÜV SÜD PRODUCT SERVICE GMBH	31.12.2028	Not Applicable
NEW MAMILAT						

Identification of the device(s) ³ (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
(REF DC 620010/02)	Families: Breast Pump Budi: 805461910Z12030303		GMBH (0123)	(0123)		
SET ACCESSORI TIRALATTE ELETTRICO (REF DC 520016)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Kit for Electric Breast Pump Budi: 805461910Z120803994A	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
CLIAMED TERMOMETRO ASCELLARE (REF TR 200050)	MDD 93/42/EEC Certificate No. G2 063105 0047 Rev.01 Families: Electronic Thermometer Budi: 805461910V03010102V9	26.05.2024	TÜV SÜD PRODUCT SERVICE GMBH (0123)	TÜV SÜD PRODUCT SERVICE GMBH (0123)	31.12.2028	Not Applicable
digiT-40 (REF TR 200030)						
digiT-40 (REF TR 200030/01)						
digiT-40F (REF TR 200040)						
digiT-40F (REF TR 200040/01)						
digiT-10P (REF TR 200300)						
TERMO FLASH CLENNY (REF TR 200300/01)						
T-Digit (REF TR 200300/02)						