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	BD Switzerland Sàrl
Manufacturer address and contact details	Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins, Switzerland
Single Registration Number (SRN) (if available)	CH-MF-000026539

Authorised Representative name (if applicable)	Becton Dickinson Ireland Limited
Authorised Representative address and contact details	Donore Road Drogheda Co. Louth A92 YW26 Ireland
Single Registration Number (SRN) (if available)	IE-AR-000007610

Notified body name (if applicable)	□ See attached schedule
Notified body number (if applicable)	□ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	□ See attached schedule

[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.

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	□ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the attached schedule, 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.

☐ 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)

☐ 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.

✓ Expired/expires *after* 20 March 2023:

✓ 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 to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or their substitute(s) and a signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 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

☐ 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:

☐ 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)**

☐ 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 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:

BD Switzerland Sàrl

Route de Crassier 17,

Business Park Terre-Bonne,

Batiment A4,

1262 Eysins,

Switzerland

Michael Campbell Senior Director Regulatory Affairs

Signed by:

Signer Name: Michael A Campbell
Signing Reason: I approve this document
Signing Time: 27-Mar-2026 | 4:35:45 AM PDT
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Michael.A.Campbell@bd.com

Schedule of Devices

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

MDD Tech File	Identification of the device(s)	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)
STED001	273-001V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-002V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-003V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-004V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-008EV	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-009V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-022V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-043V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-053V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-080EV	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-103EV	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-303EV	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-304V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-950EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-951EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-952EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED001	273-954EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	60033E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	60093E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	60103E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	60123E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	60393E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	60593	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

MDD Tech File	Identification of the device(s)	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)
STED003	60643	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	60693E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	60793E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	60950E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	60951E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	60952E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	60953V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	60985	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	63200NYB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	63260NY	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	63401EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	63420EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	63423BE	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED003	63477EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70033V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70093E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70103E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70123E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70125E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70593	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70641	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70643	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70693E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70793E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70895	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70896	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

MDD Tech File	Identification of the device(s)	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)
STED021	70950E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70951E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70952E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70953	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED021	70954E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	20021E7D	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	20041E-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	20049E7D	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	20060E7D	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	20159E7D	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	20059E-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	20350E-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	30201E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	30202E-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	30207E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	37262E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	41173E-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	42081E-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED104	42490E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	02008382189	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	03508068307	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	03508073270	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	03508079270	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	03508085440	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	03508239448	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	03508241442	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

MDD Tech File	Identification of the device(s)	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)
STED200	03508242442	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	03508364318	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	03508370319	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	04100135162	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	04108060270	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	04108074270	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	04108078411	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	MFX2250EV	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	MFX2300EV	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	MFX2301EV	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	MFX2302EV	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	MFX2304EV	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	MFX2309EV	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	MFX2310EV	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	MFX2311EV	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	388000	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	388001	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	388002	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	388003	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	388010	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	388050	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	388053	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED200	388136	CE 506414	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	04108362418	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	04108362X10	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	2305E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

MDD Tech File	Identification of the device(s)	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)
STED204	2306E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	72946NE	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	72947NE	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	72948NE	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	72949NE	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	72950NE	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	72951NE	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	72978NE	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	72979NE	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	72981NE	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	72987NE	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	72988NE	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED204	MFX2254V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED205	71980B	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
STED205	72001EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
STED205	72013EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
STED205	72024EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
STED205	72304B	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
STED205	72504EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
STED205	72643EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
STED205	72953B	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
STED205	MFX72950EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
STED205	MFX72951EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
STED205	MFX72952EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
STED205	MFX72954EB	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
STED301	MP2000C-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

MDD Tech File	Identification of the device(s)	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)
STED301	MP2002C-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED301	MP2005C-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED301	MP2202C-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED301	MP9001C-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED301	MP9027C-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED301	MP9081C-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED301	MP9213C-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED301	MP9220C-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED301	MP9240C-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED304	MP1000C-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED307	MZ1000	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED307	MZ1000-BR	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ5301	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ5302	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ5303	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ5304	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ5305	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ5306	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ5307	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ5309	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ5310	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ5312	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ5313	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ5316	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9226	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9265	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

MDD Tech File	**Identification of the device(s)**	**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)
STED308	MZ9266	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9267	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9270	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9271	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9272	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9273	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9274	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9275	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9276	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9277	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9278	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9279	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9281	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9283	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9288	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9289	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9290	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9292	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9293	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9294	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9295	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9296	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9299	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9300	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9303	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9313	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

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STED308	MZ9321	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9322	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9324	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9325	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9326	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9327	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9328	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZ9329	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZX5301	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZX5302	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZX5305	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZX5306	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZXT5303	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZXT5304	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZXT5306	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZXT5307	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZXT9001	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZXT9003	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
STED308	MZXT9004	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF036	500-002V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF036	500-003V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF036	500-012V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF036	500-013V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF036	500-021EV	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF036	500-031EV	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF036	G30302V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

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TF036	G30402M	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF036	G30453V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF036	G30454V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF036	G30653V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF036	G40020B	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF036	G40320V	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000789	72103E-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
TF10000000789	72923E-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
TF10000000789	72313-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
TF10000000789	72923-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
TF10000000789	72983-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	Yes*
TF10000000790	10010454-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	10942011-04	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	10942015-04	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	11171415-04	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	11171447-04	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	11426965-04	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	22003-0004	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	2203-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	2206-0007	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	2260-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	24006-0004	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	2401-0004	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	2401-1504	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	2420-0007	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	2420-1504	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

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TF10000000790	2426-0004	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	24302-0004	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	2432-0004	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	2434-0004	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	2441-0007	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	24604-0004	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000790	2477-0007	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000797	30852	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000799	10016073	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000799	10016242	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000799	72215N	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000800	2202E-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000800	2203E-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000800	2205E-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000800	2309E-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000800	10013365-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000800	2201-0006	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000000800	2300E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF10000008021	2000E7D	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF202	04302243317	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF202	04302260452	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF207	901-020E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF207	901-021E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF207	901-022E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF207	901-023E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TF207	901-024E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

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TF207	901-028E	CE 502238	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385100	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385101	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385103	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385106	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385108	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385150	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385151	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385155	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385156	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385157	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385158	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385161	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385162	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385163	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385164	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A
TFCE-29	385165	CE 01738	26-May-24	BSI - 2797	BSI - 2797	31-Dec-28	N/A

*SKU maintained under MDD until substitute SKU is available on the market.

Revision History

Revision	Date	Change Description
A	20-December-2023	First Release
B	09-January-2024	Corrected several CE certificate references to CE 506414. Added SKU: 500-003V.
C	19-March-2024	Addition of the following SKUs: 41173E-0006, 42081E-0006, 2203-0006, 30852, 2201-0006, 10016073, 72215N, 30207E, 10016242, 60033E, 60103E, 63260NY, 388000, 388001, 388002, 388003, 388010, 388050, 388053, 388136, 500-002V, 500-012V, 500-013V, 901-020E, 901-021E, 901-022E, 901-023E, 901-024E, 901-028E as products now planned to be CE marked under MDR.
D	31-May-2024	Addition of the following SKUs:11426965-04, 72215N as products now planned to be CE marked under MDR 72983-0006, 72953B, 72923E-0006, 72923-0006, 72313-0006, 72304B, 72103E-0006, 71980B, 72001EB, 72013EB, 72024EB, 72504EB, 72643EB, MFX72950EB, MFX72951EB, MFX72952EB, MFX72954EB as products to be maintained under MDD until substitute device is released under MDR.
E	21-June-2024	Addition of the following SKUs: 37262E, MS3500-15.
F	18-July-2024	Removal of the following SKUs: MZ9287, MZ9301, MZ9302 as product have been discontinued. Addition of the following SKUs: 20059E-0006, 30201E, 30202E-0006, 42490E as products now planned to be CE marked under MDR
G	29-August-2024	Amended text to remove ambiguity. Attached the MDR Quality Management Certificate CE 745680.
H	06 May 2025	Corrected CE certificate references for the Q-Syte devices to CE 01738
I	08 Dec 2025	Corrected address of BD Ireland as authorised representative Update change description C,D and F, to clarify reason for change Updated list of products table to include MDD Technical File and list in order of MDD Technical File, add note, to explain SE set substitute. Removed MS3500-15 as product is discontinued.
J	27-Mar-2026	Removed Texium Needle-Free Syringe (MY8003-0006, MY8005-0006, MY8010-0006, MY8020-0006, MY8030-0006, MY8060-0006), and Texium Closed Male Luer (10012241) as transitioned from MDD to MDR, now under MDR 745680.