Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

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	Becton, Dickinson and Company
Manufacturer address and contact details	1 Becton Drive Franklin Lakes, New Jersey 07417, USA
Single Registration Number (SRN) (if available)	US-MF-000019182

Authorised Representative name (if applicable)	Becton Dickinson Ireland Ltd.
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
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

[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.

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

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.

  ☒ 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 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

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

- **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: **Not applicable to the devices in the attached schedule.**

  ☐ 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: Becton, Dickinson and Company

Location & Date: Franklin Lakes, New Jersey, USA

Signature, Print Name, Title:

DocuSigned by:
Nathan Carrington
Signer Name: Nathan Carrington
Signing Reason: I approve this document
Signing Time: 01-Mar-2024 | 2:51:32 PM PST
5D0EA9C34D1D4401BADA25407286BEF2

Nate Carrington
VP, Regulatory Affairs
Contact Details: Nate.Carrington@bd.com

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

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)
367300	252.548	May-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
364810	252.548	May-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
36481000	252.548	May-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
364902	252.548	May-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
36490200	252.548	May-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367338	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367336	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367335	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367344	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367342	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367341	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367326	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367324	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367323	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367393	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367392	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367391	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367365	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367364	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367363	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367354	252.810	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367355	252.810	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367356	252.810	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368657	252.810	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368658	252.810	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368684	252.810	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368685	252.810	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A

[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)

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

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)
368686	252.810	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368687	252.810	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368688	252.810	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368689	252.810	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
362093	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
362094	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
362095	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367246	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367247	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367282	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367284	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367286	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367288	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
367295	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368382	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368383	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368652	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368653	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368654	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368655	252.191	Jun-18-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368609	252.190	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368610	252.190	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368650	252.190	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368651	252.190	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
301746	252.190	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
301747	252.190	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
365077	252.190	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
365076	252.190	May-26-2024	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368102	252.189	April-26-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A
368103	252.189	April-26-2023	NSAI 0050	NSAI 0050	Dec-31-2028	N/A

[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)