

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, NJ 07417, USA
Single Registration Number (SRN) (if available)	US-MF-000019182

Authorised Representative name (if applicable)	Becton Dickinson Distribution Center NV
Authorised Representative address and contact details	Laagstraat 57 B-9140 Temse Belgium
Single Registration Number (SRN) (if available)	NA

Notified body name (if applicable)	NSAI <input type="checkbox"/> See attached schedule
Notified body number (if applicable)	0050 <input type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	<input checked="" type="checkbox"/> 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.

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

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.

X Expired/expires *after* 20 March 2023:

Choose one applicable statement:

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

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- ☒ 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.

➤ **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.

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Signed for and on behalf of the manufacturer:

Full Company Name:

Becton Dickinson and Company

Location & Date:

Franklin Lakes, NJ

Signature, Print Name, Title:

DocuSigned by:
John W. Roberts
Signer Name: John W. Roberts
Signing Reason: I approve this document
Signing Time: 05-Jan-2024 | 12:00:12 PM PST
8B97BB78BFD4856ABBF5B27C5A103E

05-Jan-2024

John Roberts, Sr. Director Regulatory Affairs

Contact Details (at least email):

john_w_roberts@bd.com

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Schedule of Devices

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

Identification of the device(s) (catalogue number)	Identification of the device(s) (device name)	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)
300912	SYRINGE 10ML LL EUROGRAPHICS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
301033	SYRINGE 30ML LL BNS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
302830	SYRINGE 20ML LL S/C 48	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
302831	SYRINGE 20ML LS S/C 48	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
302832	SYRINGE 30ML LL S/C 56	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
302833	SYRINGE 30ML LS S/C 56	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305778	SYRINGE 1ML LL W/NDL ECLIPSE 30X1/2 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305779	SYRINGE 3ML LL W/NDL ECLIPSE 21X1 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305780	SYRINGE 1ML LL W/NDL ECLIPSE 25X5/8 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305781	SYRINGE 3ML LL W/NDL ECLIPSE 25X5/8 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305782	SYRINGE 3ML LL W/NDL ECLIPSE 23X1 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305784	SYR 3ML LL W/NDL ECLIPSE 21X1-1/2 RB TW	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305786	22 G x 1 1/2 in Eclipse™ 10 mL Luer-Lok™ syringe	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305787	SYRINGE 3ML LL W/NDL ECLIPSE 25X1 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305788	3 mL Syringe with 22G x 1" Eclipse Needle	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305789	SYRINGE 1ML LL W/NDL ECLIPSE 27X1/2 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305903	SYRINGE 1ML S/T W/NDL SFTYGLD 25X5/8 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305904	SYRINGE 3ML LL W/NDL SFTYGLD 25X5/8 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA

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305905	SYRINGE 3ML LL W/NDL SFTYGLD 23X1 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305906	3 mL Syringe w/22G x 1½ SafetyGlide™ Needle	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305909	SYR 3ML LL W/NDL SFTYGLD 21X1-1/2 RB TW	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305924	SYRINGE 3ML LL W/NDL SFTYGLD 25X1 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305927	SYRINGE 1ML S/T W/NDL SFTYGLD 27X5/8 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305934	1/2 mL SafetyGlide Insulin Syringe with 30 G TW x 5/16 in RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305945	SYRINGE SFTYGLD 1ML W/NDL 27X1/2 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305946	1 mL SafetyGlide™ Tuberculin syringe with 26 G x 3/8 in	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305950	SYRINGE ALRG SFTYGLD 1ML W/NDL 27X1/2 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305951	1 mL Allergist tray with 26 G x 3/8 in SafetyGlide	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309570**	3ML LL W/NDL 25X5/8 RB (TW)	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309571	SYRINGE 3ML LL W/NDL 23X1 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309574	3ML LL W/NDL 22X1-1/2 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309575	SYRINGE 3ML LL W/NDL 21X1 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309577	SYRINGE 3ML LL W/NDL 21X1-1/2 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309578	3ML LL W/NDL 20X1 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309579	3ML LL W/NDL 20X1-1/2 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309581**	3ML LL W/NDL 25X1 RB (TW)	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309582**	3ML LL W/NDL 25X1-1/2 RB (TW)	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309620	SYRINGE CATHETER TIP	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309623	SYRINGE 1ML S/T W/NDL 27X1/2 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309624	SYRINGE 1ML S/T W/NDL 21X1 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309625	1ml TB Syringe Slip Tip W/NDL 26G x 3/8	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309626	1ml TB Syringe Slip Tip with BD	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309628	SYRINGE 1ML LL	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA

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309649	SYRINGE 5ML LL EURO 125 S/C	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309653	SYRINGE 60ML LL TIP 1ML	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309654	SYRINGE 60ML S/T LATEX FREE CONFIGURE	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309658	SYRINGE 3ML LL EURO 200 S/C	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400048	SYRINGE 3ML L/T BNS NRFIT	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400049	SYRINGE 5ML S/T BNS NRFIT	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400050	SYRINGE 3ML L/T SSU NRFIT	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400051	SYRINGE 5ML S/T SSU NRFIT	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400166	SYRINGE 3ML S/T BNS NRFIT	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400167	SYRINGE 5ML L/T BNS NRFIT	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400168	SYR 10ML L/T BNS NRFIT WWS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400169	SYR 10ML S/T BNS NRFIT WWS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400172	SYRINGE 3ML S/T SSU NRFIT	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400173	SYRINGE 5ML L/T SSU NRFIT	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400174	SYR 10ML L/T SSU NRFIT WWS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400175	SYR 10ML S/T SSU NRFIT WWS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400178	SYRINGE 20ML L/T BNS NRFIT	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400179	SYRINGE 50ML L/T BNS NRFIT	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400182	SYRINGE 20ML L/T SSU NRFIT	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400183	SYRINGE 50ML L/T SSU NRFIT	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
301027*	SYRINGE 5ML LL BNS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
301029*	SYRINGE 10ML LL BNS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
301030*	Syringe 10ml S/T BNS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
301031*	SYRINGE 20ML LL BNS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
301035*	SYRINGE 50ML LL BNS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
301073*	SYRINGE 3ML LL BNS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
301077*	SYRINGE 3ML S/T BNS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303306**	SYRINGE 3ML LL ECLIPSE 23X1-1/2 RB TW	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303307**	SYRINGE 5ML LL 23X1-1/2IN ECLIPSE RB TW	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303321**	SYR 10ML LL W/NDL ECLIPSE 21X1-1/2 RB TW	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303327**	SYRINGE SAFETYGLIDE 1ML W/NDL 27X3/8 IB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA

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305783	22 G x 1 1/2 in Eclipse™ 3 mL Luer-Lok™ syringe	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305785	22 G x 1 1/2 in Eclipse™ 5 mL Luer-Lok™ syringe	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305930	1 mL SafetyGlide™ insulin syringe with 29 G x 1/2 in	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305932	1/2 mL SafetyGlide™ insulin syringe with 29 G x 1/2 in RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305935	3/10 mL SafetyGlide™ insulin syringe with 29 G x 1/2 in RB`	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305937	3/10 mL SafetyGlide Insulin Syringe with 31 G TW x 5/16 in RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
309648*	SYRINGE 1ML LL BNS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
302436	27 G x 1 ½ in Eclipse Needle SmartSlip	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
302437	NEEDLE 18X1-1/2 ECLIPSE	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303671	NEEDLE ECLIPSE S/T 18GA X 1-1.2 IN RB TW CE BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303672	20 G x 1 in RB TW Eclipse Needle SmartSlip BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303673	20 G x 1 ½ in RB TW Eclipse Needle SmartSlip BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303674	NEEDLE ECLIPSE S/T 21X1-1/2 RB TW CE BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303675	22 G x 1 ¼ in RB TW Eclipse Needle SmartSlip BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303676	NEEDLE ECLIPSE S/T 23GA 1IN RB TW CE BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303677	23 G x 1 ¼ in RB TW Eclipse Needle SmartSlip BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303678	NEEDLE ECLIPSE S/T 25GA 1IN RB TW CE BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305136	NEEDLE 27X1-1/4 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305196	18G X 1½" NEEDLE	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305757	NEEDLE ECLIPSE 30X1/2	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305758	NEEDLE ECLIPSE 27X1/2	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305759	NEEDLE ECLIPSE 25X5/8	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305760	NEEDLE ECLIPSE S/T 25X5/8 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305761	NEEDLE ECLIPSE 25X1 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305762	NEEDLE ECLIPSE 23X1 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305763	22 G x 1 ½ in Eclipse Needle	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA

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305764	NEEDLE ECLIPSE 21X1 RB TW	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305765	NEEDLE ECLIPSE 21X1-1/2 RB TW	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305766	NEEDLE ECLIPSE 18X1-1/2 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305767	NEEDLE ECLIPSE 25X1-1/2 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305768	22 G x 1 in Eclipse Needle	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305769	23 G x 1 ¼ in Eclipse Needle	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305770	NEEDLE ECLIPSE S/T 27X1/2 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305771	NEEDLE ECLIPSE S/T 30X1/2 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305791	NEEDLE ECLIPSE 21X1 RB TW BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305792	NEEDLE ECLIPSE 21X1-1/2 RB TW BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305793	NEEDLE ECLIPSE 22X1-1/2 RB BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305794	NEEDLE ECLIPSE 23X1 RB BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305797	NEEDLE ECLIPSE 22X1 RB BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305798	25 G x 5/8 in Eclipse Needle BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305814	30 G X ½ in Eclipse Needle BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305886	23 G x 1 ¼ in Eclipse Needle SmartSlip	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305887	22 G x 1 ¼ in Eclipse Needle SmartSlip	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305888	20G X 1 ½ in Eclipse Needle SmartSlip	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305889	27 G X ¾ in Eclipse Needle SmartSlip	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305891	NEEDLE ECLIPSE S/T 25X1 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305892	NEEDLE ECLIPSE S/T 23X1 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305894	NEEDLE ECLIPSE S/T 21X1 RB TW	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305895	NEEDLE ECLIPSE S/T 21X1-1/2 RB TW	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305899	20 G x 1 in Eclipse Needle SmartSlip	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305900	22 G x 1 ½ in SafetyGlide Needle	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305901	NEEDLE SFTYGLD 25X5/8 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA

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305902	NEEDLE SFTYGLD 23X1 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305915	NEEDLE SFTYGLD 21X1 RB TW	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305916	NEEDLE SFTYGLD 25X1 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305917	NEEDLE SFTYGLD 21X1-1/2 RB TW	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305918	NEEDLE SFTYGLD 18X1-1/2 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305921	NEEDLE SFTYGLD 27X5/8 RB	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303005**	NEEDLE 18X1-1/2 RB NS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303278**	NEEDLE ECLIPSE 23X1-1/2 RB TW BNS	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
303304**	NEEDLE ECLIPSE 23X1-1/2 RB TW	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
304387**	NEEDLE SAFETYGLIDE 23X1-1/2 RB TW	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305106**	30G X 1/2" NEEDLE	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305127**	25G X 1 1/2" NEEDLE	CE 252.232	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
300779	NEEDLE 18X1-1/2 NOKOR	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
300780	NEEDLE 16X1IN NOKOR	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305180	NEEDLE 18X1-1/2 BLUNT FILL	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305181	NEEDLE 18X1IN BLUNT FILL	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305207	SYRINGE ORAL 1ML AMBER	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305208	SYRINGE ORAL 5ML AMBER	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305209	SYRINGE ORAL 10ML AMBER	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305210	SYRINGE ORAL 3ML AMBER	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305211	NEEDLE FILTER BLUNT FILL 18X1-1/2	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305217	SYRINGE ORAL 1ML CLEAR	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305218	SYRINGE ORAL 5ML CLEAR	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305219	SYRINGE ORAL 10ML CLEAR	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305220	SYRINGE ORAL 3ML CLEAR	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400066	NEEDLE FILTER BLUNT FILL 18X1-1/2 NRFIT SSU	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400067	NEEDLE BLUNT FILL 18X1-1/2 NRFIT SSU	CE 252.308	2-Feb-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
400106	NEEDLE SPINAL S/SU 23GA 3-1/2IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400366	NEEDLE SPINAL S/SU 22GA 5IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA

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400367	NEEDLE SPINAL S/SU 22GA 7IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400368	NEEDLE SPINAL S/SU 20GA 6IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400369	NEEDLE SP S/SU 25GA 4-11/16IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400370	NEEDLE SPINAL S/SU 18GA 6IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400371	NEEDLE SP S/SU 27GA 4-11/16IN WHITACRE	CE 252.797 AEMPS: 2010 02 0699 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400372	NEEDLE SP S/SU 25GA 4-11/16IN WHITACRE	CE 252.797 AEMPS: 2010 02 0699 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400373	NEEDLE SPINAL S/SU 25GA TW 5IN WHITACRE	CE 252.797 AEMPS: 2010 02 0699 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400374	NEEDLE SPINAL S/SU 27GA TW 5IN WHITACRE	CE 252.797 AEMPS: 2010 02 0699 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400376	NEEDLE SPINAL S/SU 25GA 2IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400377	NEEDLE SPINAL S/SU 20GA 1-1/2IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400378	NEEDLE SPINAL S/SU 18GA 3IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400379	NEEDLE SPINAL S/SU 22GA 3-1/2IN WHITACRE	CE 252.797 AEMPS: 2010 02 0699 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400380	NEEDLE SPINAL S/SU 27GA 3-1/2IN WHITACRE	CE 252.797 AEMPS: 2010 02 0699 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400381	NEEDLE SP S/SU 24GA TW 3-1/2IN WHITACRE	CE 252.797 AEMPS: 2010 02 0699 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
400382	NEEDLE SP S/SU 25GA TW 3-1/2IN WHITACRE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050	31-Dec-27	NA

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		AEMPS: 2010 02 0699 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318		
400435	NEEDLE SPINAL BNS 18GA 3-1/2IN QUINCKE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2010 02 0698 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA
400437	NEEDLE SPINAL BNS 22GA 2-1/2IN QUINCKE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2010 02 0698 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA
400441	NEEDLE SPINAL BNS 25GA 3IN QUINCKE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2010 02 0698 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA
400443	NEEDLE SPINAL 25GA X 103MM WHITACRE BULK	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2010 02 0699 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA
400444	NEEDLE SPINAL 27GA X 103MM WHITACRE BULK	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2010 02 0699 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA
400476	NEEDLE SPINAL BNS 26GA 3-1/2IN QUINCKE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2010 02 0698 ET	AEMPS:17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA
400477	NEEDLE SPINAL BNS 22GA 1-1/2IN QUINCKE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2010 02 0698 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA
400479	NEEDLE SPINAL BNS 25GA 2IN QUINCKE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2010 02 0698 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA
400496	NEEDLE SPINAL BNS 25GA 3-1/2IN QUINCKE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2010 02 0698 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA
400497	NEEDLE SPINAL BNS 22GA 3-1/2IN QUINCKE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2010 02 0698 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA
400498	NEEDLE SPINAL BNS 20GA 3-1/2IN QUINCKE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2010 02 0698 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA
400540	NEEDLE SPINAL BNS 22GA 7IN QUINCKE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2010 02 0698 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA
400616	NEEDLE SP BNS 24GA TW 3-1/2IN WHITACRE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2017 06 0860 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA
400621	NEEDLE SP BNS 25GA TW 3-1/2IN WHITACRE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050		
		AEMPS: 2010 02 0699 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318	31-Dec-27	NA

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405071	NEEDLE SPINAL S/SU 20GA 2-1/2IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405074	NEEDLE SPINAL S/SU 22GA 2-1/2IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405081	NEEDLE SPINAL S/SU 27GA 3-1/2IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405155	NEEDLE SPINAL BNS 27GA 3-1/2IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405157	NEEDLE SPINAL BNS 22GA 3-1/2IN WHITACRE	CE 252.797 AEMPS: 2010 02 0699 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405159	NEEDLE SPINAL BNS 27GA 3-1/2IN WHITACRE	CE 252.797 AEMPS: 2010 02 0699 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405161	NEEDLE SPINAL S/SU 22GA 1-1/2IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405164	NEEDLE SPINAL S/SU 26GA 3-1/2IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405170	NEEDLE SPINAL S/SU 25GA 3IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405171	NEEDLE SPINAL S/SU 22GA 3IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405172	NEEDLE SPINAL S/SU 20GA 3IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405180	NEEDLE SPINAL S/SU 25GA 3-1/2IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405181	NEEDLE SPINAL S/SU 22GA 3-1/2IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405182	NEEDLE SPINAL S/SU 20GA 3-1/2IN QUINCKE	CE 252.797 AEMPS: 2010 02 0698 ET	26-May-24; 17 Dec 2023	NSAI; 0050 AEMPS' 0318	NSAI; 0050 AEMPS' 0318	31-Dec-27	NA
405184	NEEDLE SPINAL S/SU 18GA 3-1/2IN QUINCKE	CE 252.797	26-May-24;	NSAI; 0050	NSAI; 0050	31-Dec-27	NA

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		AEMPS: 2010 02 0698 ET	17 Dec 2023	AEMPS' 0318	AEMPS' 0318		
300912	SYRINGE 10ML LL EUROGRAPHICS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
301033	SYRINGE 30ML LL BNS	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
302830	SYRINGE 20ML LL S/C 48	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
302831	SYRINGE 20ML LS S/C 48	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
302832	SYRINGE 30ML LL S/C 56	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
302833	SYRINGE 30ML LS S/C 56	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305778	SYRINGE 1ML LL W/NDL ECLIPSE 30X1/2 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305779	SYRINGE 3ML LL W/NDL ECLIPSE 21X1 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305780	SYRINGE 1ML LL W/NDL ECLIPSE 25X5/8 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305781	SYRINGE 3ML LL W/NDL ECLIPSE 25X5/8 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305782	SYRINGE 3ML LL W/NDL ECLIPSE 23X1 RB	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305784	SYR 3ML LL W/NDL ECLIPSE 21X1-1/2 RB TW	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA
305786	22 G x 1 1/2 in Eclipse™ 10 mL Luer-Lok™ syringe	CE 252.231	26-May-24	NSAI; 0050	NSAI; 0050	31-Dec-28	NA

* This product is a non-sterile (intended to be sterilized prior to use by a kit manufacturer) equivalent of a product under review

** This product is a substitute SKU for product under review, or being substituted by a product under review

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