




E-Manufacturer's Certificate to Export Licensed Medical Devices from Canada-Certificate of Free Sale (FRM-0539)

We, the undersigned manufacturer of the following devices:

Part 1 – Devices (include the MDEL information for your Class I medical device and the MDL information for your Class II, III and IV medical devices)			
Medical Devices Establishment Licence (MDEL)			
MDEL # (Class I medical devices):		Device(s) name:	
Medical Device Licence (MDL)			
MDL #: 96982	Device identifier: (model/catalogue detail) CR2-LF11N-2QMQM	MDL Class #: (II, III, IV) II	Device(s) name: REUSABLE BLOOD PRESSURE CUFF (Part Number: CR2-LF##X-#XXXX)
Interim Order (IO) authorizations			
IO authorization ID #:	Device(s) name:	IO authorization date: (yyyy-mm-dd)	Device identifier #:
<p>Do hereby certify that:</p> <ul style="list-style-type: none"> a) each device is manufactured, produced and sold in Canada in accordance with the requirements of Canada's <i>Food and Drugs Act</i> and the <i>Medical Device Regulations</i> thereunder b) tests have been conducted for each device and the tests indicate that the nature of the benefits claimed to be obtained through the use of each device and the performance characteristics of each device are justified 			
Part 2 - Name and address of manufacturer			
Company ID (6 digits): 135034	Name: Amico Diagnostic Incorporated		
Street address: 122 East Beaver Creek Rd			
City: Richmond Hill	Province: Ontario	Postal code: L4B 1G6	
Part 3 – Signature of authorized person (print name and title of the authorized person)			
Name: Jack Chang, Quality Manager		Signature:  Digitally signed by Jack Chang Date: 2023.04.18 10:20:47 -04'00'	

Medical Device Licence (MDL) – Additional			
MDL#	Device identifier (model/catalogue detail)	MDL Class # (II, III, IV)	Device(s) name
96982	CR2-LF11N-1	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-1BM	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-1KF	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-1LF	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-1QF	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-1QM	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-1SM	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2BM	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2BMBM	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2BMBV	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2BV	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2BVBM	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2BVKF	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2BVLF	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2BVSF	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2BVSM	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2KF	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2LF	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2QFQF	II	REUSABLE BLOOD PRESSURE CUFF - ADULT
96982	CR2-LF11N-2QFQM	II	REUSABLE BLOOD PRESSURE CUFF - ADULT

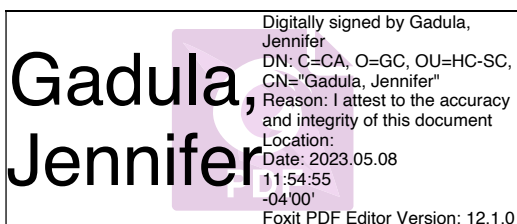
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Health Canada
Regulatory Operations and Enforcement Branch

It is hereby certified that:

- Devices manufactured, produced and sold in the manner above described would not, by reason of the method of manufacture thereof, be in violation of the Act and the Regulations thereunder
- Devices manufactured and sold in compliance with the Act and the Regulations may be exported without restriction
- Devices listed are registered and sold in Canada and are of free sale



Medical Devices Establishment Licence Unit
Medical Devices and Clinical Compliance Directorate
Regulatory Operations and Enforcement Branch
Health Canada

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Privacy Notice

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Name: Jack Chang, Quality Manager		Signature: Jack Chang Digitally signed by Jack Chang Date: 2023.04.18 10:20:47 -04'00'	

Medical Device Licence (MDL) – Additional			
MDL#	Device identifier (model/catalogue detail)	MDL Class # (II, III, IV)	Device(s) name
96982	CR2-LF09G-1	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-1BM	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-1KF	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-1LF	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-1QF	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-1QM	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-1SM	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2BM	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2BMBM	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2BMBV	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2BV	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2BVBM	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2BVKF	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2BVLF	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2BVSF	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2BVSM	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2KF	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2LF	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2QFQF	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-2QFQM	II	REUSABLE BLOOD PRESSURE CUFF - CHILD

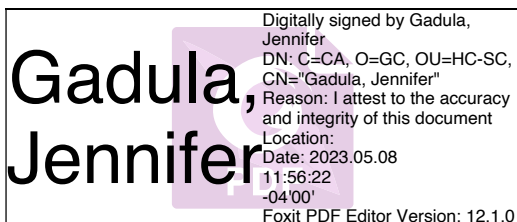
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Interim Order (IO) authorizations			
IO authorization ID #:	Device(s) name:	IO authorization date: (yyyy-mm-dd)	Device identifier #:
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Part 3 – Signature of authorized person (print name and title of the authorized person)			
Name: Jack Chang, Quality Manager		Signature: Jack Chang Digitally signed by Jack Chang Date: 2023.05.04 11:55:34 -04'00'	

Medical Device Licence (MDL) – Additional			
MDL#	Device identifier (model/catalogue detail)	MDL Class # (II, III, IV)	Device(s) name
96982	CR2-LF09G-2SMSM	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF070-1	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF09G-1KF	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-1LF	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF09G-1QF	II	REUSABLE BLOOD PRESSURE CUFF - CHILD
96982	CR2-LF070-1BM	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-1KF	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-1LF	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-1QF	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-1QM	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-1SM	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-2	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-2BM	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-2BMBM	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-2BMBV	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-2BV	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-2BVBM	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-2BVKF	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-2BVLF	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-2BVSF	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-2BVSM	II	REUSABLE BLOOD PRESSURE CUFF - INFANT

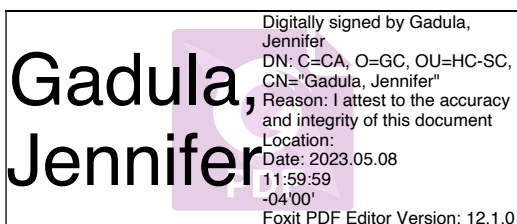
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96982	CR2-LF070-2QFQF	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-2QFQM	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-2QMQM	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF070-2SMSM	II	REUSABLE BLOOD PRESSURE CUFF - INFANT
96982	CR2-LF12M-1	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-1BM	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-1KF	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-1LF	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-1QF	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-1QM	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-1SM	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-2	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-2BM	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-2BMBM	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-2BMBV	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-2BV	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-2BVBM	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-2BVKF	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-2BVLF	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-2BVSF	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT

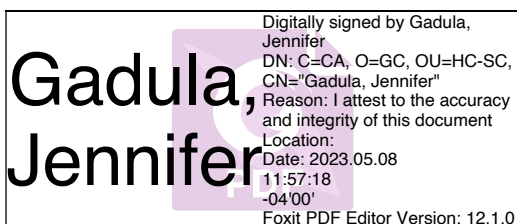
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96982	CR2-LF12M-2QFQF	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-2QFQM	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-2QMQM	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF12M-2SMSM	II	REUSABLE BLOOD PRESSURE CUFF - LARGE ADULT
96982	CR2-LF10B-1	II	REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT
96982	CR2-LF10B-1BM	II	REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT
96982	CR2-LF10B-1KF	II	REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT
96982	CR2-LF10B-1LF	II	REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT
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96982	CR2-LF10B-2BVKF	II	REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT
96982	CR2-LF10B-2BVLF	II	REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT

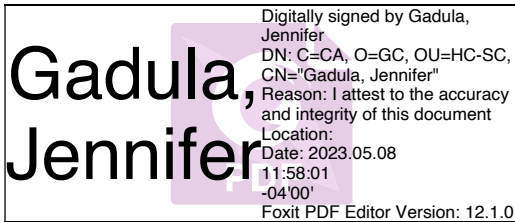
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It is hereby certified that:

- Devices manufactured, produced and sold in the manner above described would not, by reason of the method of manufacture thereof, be in violation of the Act and the Regulations thereunder
- Devices manufactured and sold in compliance with the Act and the Regulations may be exported without restriction
- Devices listed are registered and sold in Canada and are of free sale



Medical Devices Establishment Licence Unit
Medical Devices and Clinical Compliance Directorate
Regulatory Operations and Enforcement Branch
Health Canada

Disclaimer: This certificate is valid only if signed by Health Canada with all pages included. The validity of the signature can only be viewed electronically.

Privacy Notice

The personal information you provide to Health Canada will be used by the Regulatory Operations and Enforcement Branch under the *Food and Drug Act* and the *Medical Devices Regulations* and handled in accordance with the *Privacy Act*.

Why are we collecting your personal information? We require your personal information, including your name, title and manufacturer information to process your request for a Manufacturer's Certificate to Export Licensed Medical Devices from Canada.

Will we use or share your personal information for any other reason? We may also share your personal information with Global Affairs Canada to authenticate the certificate.


What happens if you don't want to provide your personal information? Failure to provide the requested information may prevent the processing of your request for a Manufacturer's Certificate to Export Licensed Medical Devices from Canada.

What are your rights? You have the right to access and request a correction and/or notation to your personal information. You also have a right to complain to the Privacy Commissioner of Canada if you feel your personal information has been handled improperly. For more information about these rights or about how we handle your personal information, please contact us by email at mce.questions-cfe@hc-sc.gc.ca.



E-Manufacturer's Certificate to Export Licensed Medical Devices from Canada - Certificate of Free Sale (FRM-0539)

We, the undersigned manufacturer of the following devices:

Part 1 – Devices <small>(include the MDEL information for your Class I medical device and the MDL information for your Class II, III and IV medical devices)</small>			
Medical Devices Establishment Licence (MDEL)			
MDEL # (Class I medical devices):		Device(s) name:	
Medical Device Licence (MDL)			
MDL #: 96982	Device identifier: <small>(model/catalogue detail)</small> CR2-LF10B-2BVSF	MDL Class #: <small>(II, III, IV)</small> II	Device(s) name: REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT <small>(Part Number: CR2-LF##X-#XXXX)</small>
Interim Order (IO) authorizations			
IO authorization ID #:	Device(s) name:	IO authorization date: <small>(yyyy-mm-dd)</small>	Device identifier #:
<p>Do hereby certify that:</p> <ul style="list-style-type: none"> a) each device is manufactured, produced and sold in Canada in accordance with the requirements of Canada's <i>Food and Drugs Act</i> and the <i>Medical Device Regulations</i> thereunder b) tests have been conducted for each device and the tests indicate that the nature of the benefits claimed to be obtained through the use of each device and the performance characteristics of each device are justified 			
Part 2 - Name and address of manufacturer			
Company ID (6 digits): 135034	Name: Amico Diagnostic Incorporated		
Street address: 122 East Beaver Creek Rd			
City: Richmond Hill	Province: Ontario	Postal code: L4B 1G6	
Part 3 – Signature of authorized person (print name and title of the authorized person)			
Name: Jack Chang, Quality Manager		Signature:  Digitally signed by Jack Chang Date: 2023.04.18 10:20:47 -04'00'	

Medical Device Licence (MDL) – Additional			
MDL#	Device identifier (model/catalogue detail)	MDL Class # (II, III, IV)	Device(s) name
96982	CR2-LF10B-2BVSM	II	REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT
96982	CR2-LF10B-2KF	II	REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT
96982	CR2-LF10B-2LF	II	REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT
96982	CR2-LF10B-2QFQF	II	REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT
96982	CR2-LF10B-2QFQM	II	REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT
96982	CR2-LF10B-2QMQM	II	REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT
96982	CR2-LF10B-2SMSM	II	REUSABLE BLOOD PRESSURE CUFF - SMALL ADULT
96982	CR2-LF13W-1	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-1BM	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-1KF	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-1LF	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-1QF	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-1QM	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-1SM	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-2	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-2BM	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-2BMBM	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-2BMBV	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-2BV	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-2BVBM	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-2BVKF	II	REUSABLE BLOOD PRESSURE CUFF- THIGH

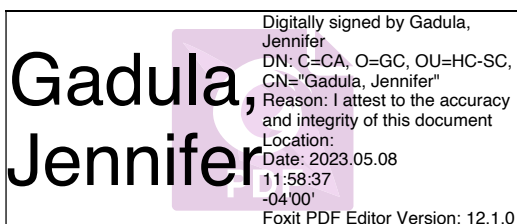
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Medical Device Licence (MDL)			
MDL #: 96982	Device identifier: (model/catalogue detail) CR2-LF13W-2BVLV	MDL Class #: (II, III, IV) II	Device(s) name: REUSABLE BLOOD PRESSURE CUFF- THIGH (Part Number: CR2-LF##X-#XXXX)
Interim Order (IO) authorizations			
IO authorization ID #:	Device(s) name:	IO authorization date: (yyyy-mm-dd)	Device identifier #:
Do hereby certify that:			
<ul style="list-style-type: none"> a) each device is manufactured, produced and sold in Canada in accordance with the requirements of Canada's <i>Food and Drugs Act</i> and the <i>Medical Device Regulations</i> thereunder b) tests have been conducted for each device and the tests indicate that the nature of the benefits claimed to be obtained through the use of each device and the performance characteristics of each device are justified 			
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Name: Jack Chang, Quality Manager		Signature: Jack Chang Digitally signed by Jack Chang Date: 2023.04.18 10:20:47 -04'00'	

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96982	CR2-LF13W-2BVSM	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-2KF	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-2LF	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-2QFQF	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-2QFQM	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-2QMQM	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
96982	CR2-LF13W-2SMSM	II	REUSABLE BLOOD PRESSURE CUFF- THIGH
97186	CR2-BLDR07R-1	II	BLOOD PRESSURE CUFF BLADDER
97186	CR2-BLDR07R-2	II	BLOOD PRESSURE CUFF BLADDER
97186	CR2-BLDR09R-1	II	BLOOD PRESSURE CUFF BLADDER
97186	CR2-BLDR09R-2	II	BLOOD PRESSURE CUFF BLADDER
97186	CR2-BLDR10R-1	II	BLOOD PRESSURE CUFF BLADDER
97186	CR2-BLDR10R-2	II	BLOOD PRESSURE CUFF BLADDER
97186	CR2-BLDR11R-1	II	BLOOD PRESSURE CUFF BLADDER
97186	CR2-BLDR11R-2	II	BLOOD PRESSURE CUFF BLADDER
97186	CR2-BLDR12R-1	II	BLOOD PRESSURE CUFF BLADDER
97186	CR2-BLDR12R-2	II	BLOOD PRESSURE CUFF BLADDER
97186	CR2-BLDR13R-1	II	BLOOD PRESSURE CUFF BLADDER
97186	CR2-BLDR13R-2	II	BLOOD PRESSURE CUFF BLADDER

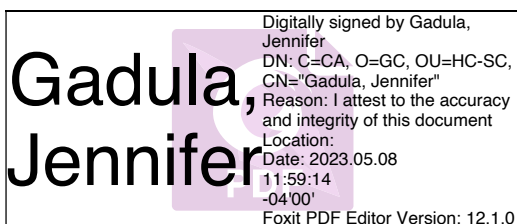
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