

SCRUB CARE EXIDINE -4 CHG- chlorhexidine gluconate liquid
Xttrium Laboratories, Inc.

Drug Facts CareFusion 4%

Active Ingredients

Chlorhexidine Gluconate 4% Solution

Purpose

Antiseptic

Uses

surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care

healthcare personnel handwash: helps reduce bacteria that potentially can cause disease

patient preoperative skin preparation: for the preparation of the patient's skin prior to surgery

skin wound and general skin cleansing

Warnings

For external use only

Allergy alert:

This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- in contact with meninges
- in the genital area
- as a preoperative skin preparation of the head or face

When using this product

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures or may cause deafness when instilled in the middle ear through perforated eardrums
- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when advised by a health care provider

Stop use and ask a doctor if

irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

Surgical hand scrub:

- wet hands and forearms with water
- scrub for 3 minutes with about 5 mL of product and a wet brush, paying close attention to the nails, cuticles, and interdigital spaces
- a separate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 5 mL of product and rinse under running water
- dry thoroughly

Healthcare personnel handwash:

- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in vigorous manner for about 15 seconds
- rinse and dry thoroughly

Patient preoperative skin preparation:

- apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel
- repeat procedure for an additional 2 minutes and dry with a sterile towel

Skin wound and general skin cleansing:

- thoroughly rinse the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently
- rinse again thoroughly

Other information

- store at 20°-25° C (68°-77° F)
- avoid excessive heat above 40° C (104° F)

Inactive ingredients

cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol

Questions or comments?

Call **1-800-587-3721**

Monday through Friday 8:00 AM to 4:30 PM CST

Package label and principal display panel

NDC 0116-2994-04

REF 29900-404

BD Scrub Care™

Exidine™-4 CHG 4%

Chlorhexidine Gluconate 4% Solution

Antiseptic

Non-sterile Solution

Contains:

4% Chlorhexidine Gluconate

For External Use Only

For Single Use Only

Distributed By

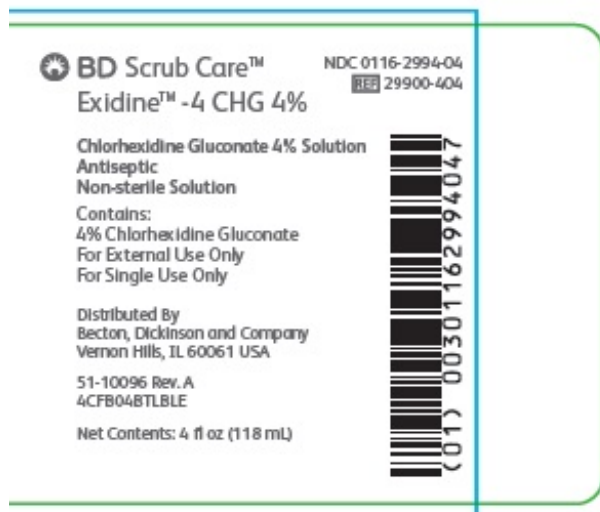
Becton, Dickinson and Company

Vernon Hills, IL 60061 USA

51-10096 Rev. A

4CFB04BTLBLE

Net Contents: 4 fl oz (118 mL)



Drug Facts

Active Ingredient

Chlorhexidine gluconate

4% solution Antiseptic

Purpose

Uses

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel handwash:** helps reduce bacteria that potentially can cause disease
- **patient preoperative skin preparation:** for the preparation of the patient's skin prior to surgery
- **skin wound and general skin cleansing**

Lift Here

Drug Facts (continued)

Warnings

For external use only

Allergy alert:

This product may cause a severe allergic reaction.

Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- in contact with meninges
- in the genital area
- as a preoperative skin preparation of the head or face

When using this product

- keep out of the eyes, ears and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures or may cause deafness when instilled in the middle ear through perforated eardrums
- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when advised by a health care provider

Drug Facts (continued)

Stop use and ask doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

Surgical hand scrub:

- wet hands and forearms with water
- scrub for 3 minutes with about 5 mL of product and a wet brush paying close attention to the nails, cuticles, and interdigital spaces
- a separate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 5 mL of product and rinse under running water
- dry thoroughly

Healthcare personnel handwash:

- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 15 seconds
- rinse and dry thoroughly

Patient preoperative skin preparation:

- apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel



Drug Facts (continued)

- repeat procedure for an additional 2 minutes and dry with a sterile towel

Skin wound and general skin cleaning:

- thoroughly rinse the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently
- rinse again thoroughly

Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol

Questions or comments?

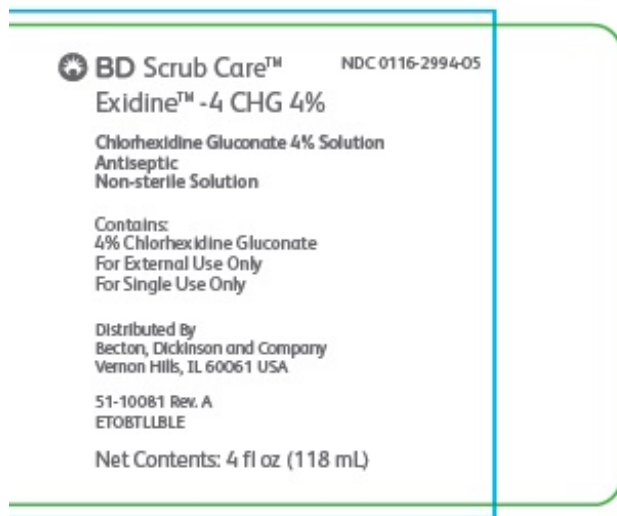
call 1-800-587-3721

Monday through Friday 8:00 AM to 4:30 PM CST

Laundering/Cleaning Instructions:

Chlorhexidine gluconate skin cleansers will cause stains if used with chlorine releasing products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.

NDC 0116-2994-05
BD Scrub Care™
Exidine™-4 CHG 4%
Chlorhexidine Gluconate 4% Solution
Antiseptic
Non-sterile Solution
Contains:
4% Chlorhexidine Gluconate
For External Use Only
For Single Use Only
Distributed By
Becton, Dickinson and Company
Vernon Hills, IL 60061 USA
51-10081 Rev. A
ETOBTLBLE
Net Contents: 4 fl oz (118 mL)



NDC 0116-2994-08
REF 29900-408
BD Scrub Care™
Exidine™-4 CHG 4%
Chlorhexidine Gluconate
4% Solution
Antiseptic
Contains: 4% Chlorhexidine Gluconate
For External Use Only
Distributed by

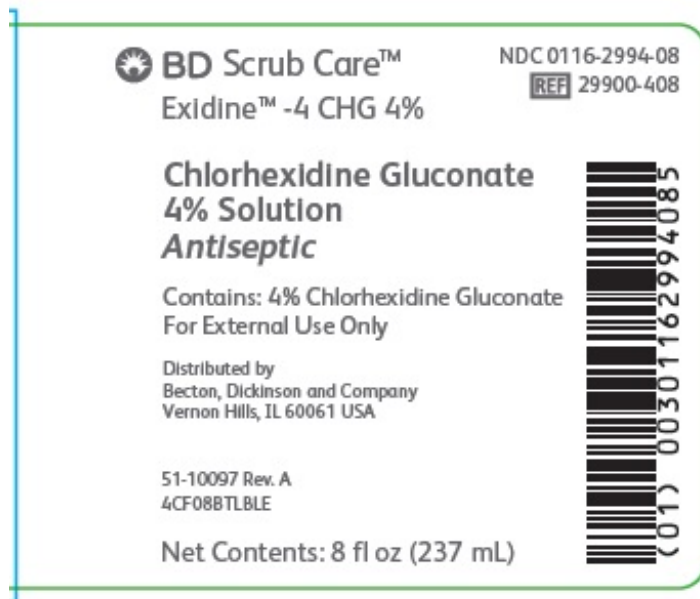
Becton, Dickinson and Company

Vernon Hills, IL 60061 USA

51-10097 Rev. A

4CF08BTLBLE

Net Contents: 8 fl oz (237 mL)



NDC 0116-2994-16

REF 29900-416

BD Scrub Care™

Exidine™-4 CHG 4%

Chlorhexidine Gluconate

4% Solution

Antiseptic

Contains:

4% Chlorhexidine Gluconate

For External Use Only

Distributed By

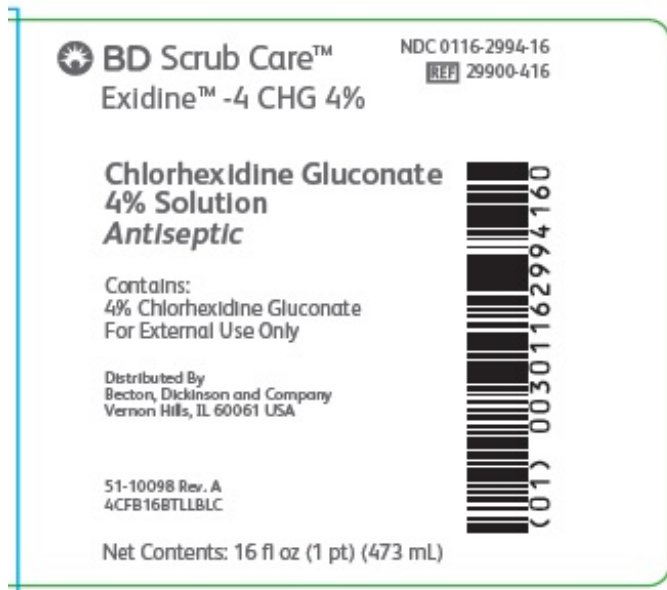
Becton, Dickinson and Company

Vernon Hills, IL 60061 USA

51-10098 Rev. A

4CFB16BTLLBLC

Net Contents: 16 fl oz (1 pt) (473 mL)



NDC 0116-2994-17

REF 29900-416P

BD Scrub Care™

Exidine™-4 CHG 4%

Chlorhexidine Gluconate

4% Solution

Antiseptic

Contains:

4% Chlorhexidine Gluconate

For External Use Only

Distributed By

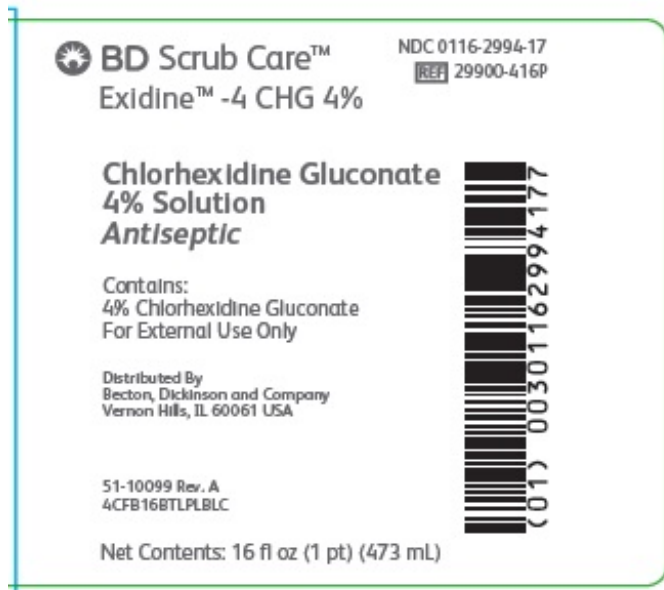
Becton, Dickinson and Company

Vernon Hills, IL 60061 USA

51-10099 Rev. A

4CFB16BTLPLBLC

Net Contents: 16 fl oz (1 pt) (473 mL)



NDC 0116-2994-32

REF 29900-432

BD Scrub Care™

Exidine™-4 CHG 4%

Chlorhexidine Gluconate

4% Solution

Antiseptic

Contains: 4% Chlorhexidine Gluconate

For External Use Only

Distributed by

Becton, Dickinson and Company

Vernon Hills, IL 60061 USA

51-10100 Rev. A

4CFB32BTLLBLC

Net Contents: 32 fl oz (1 qt) (946 mL)

BD Scrub Care™
Exidine™ -4 CHG 4%

NDC 0116-2994-32
REF 29900-432

Chlorhexidine Gluconate 4% Solution Antiseptic

Contains: 4% Chlorhexidine Gluconate
For External Use Only

Distributed by
Becton, Dickinson and Company
Vernon Hills, IL 60061 USA

51-10100 Rev. A
4CFB32BTLBLCL



Net Contents: 32 fl oz (1 qt) (946 mL)

Drug Facts

Active Ingredient	Purpose
Chlorhexidine gluconate 4% solution	Antiseptic

Uses

- surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- healthcare personnel handwash: helps reduce bacteria that potentially can cause disease
- skin wound and general skin cleansing

Warnings
For external use only

Allergy alert:
This product may cause a severe allergic reaction. Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

- if you or the patient is allergic to chlorhexidine gluconate or any other ingredient in this product
- in contact with meringues
- in the genital area

When using this product

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when advised by a health care provider

Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.
Keep out of reach of children.
If swallowed, get medical help or contact a Poison Control Center right away. ▶

Drug Facts (continued)

Directions
Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

Surgical hand scrub:

- wet hands and forearms with water
- scrub for 3 minutes with about 5 mL of product and a wet brush paying close attention to the nails, cuticles, and interdigital spaces
- a separate nail cleaner may be used
- rinse thoroughly
- wash for an additional 3 minutes with 5 mL of product and rinse under running water
- dry thoroughly

Healthcare personnel handwash:

- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for about 15 seconds
- rinse and dry thoroughly

Skin wound and general skin cleansing:

- thoroughly rinse the area to be cleaned with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently
- rinse again thoroughly

Other Information

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive Ingredients cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, triethyl alcohol

Questions or comments?
call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST

NDC 0116-2994-33

REF 29900-432P

BD Scrub Care™

Exidine™-4 CHG 4%

Chlorhexidine Gluconate

4% Solution

Antiseptic

Contains: 4% Chlorhexidine Gluconate

For External Use Only

Distributed by

Becton, Dickinson and Company

Vernon Hills, IL 60061 USA

51-10101 Rev. A

4CF32BTLPLBLC

Net Contents: 32 fl oz (1 qt) (946 mL)

BD Scrub Care™
Exidine™ -4 CHG 4%

NDC 0116-2994-33
REF 29900-432P

Chlorhexidine Gluconate 4% Solution Antiseptic

Contains: 4% Chlorhexidine Gluconate
For External Use Only

Distributed by
Becton, Dickinson and Company
Vernon Hills, IL 60061 USA

51-10101 Rev. A
4CF32BTLPLBLC



Net Contents: 32 fl oz (1 qt) (946 mL)

Drug Facts

Active ingredient	Purpose
Chlorhexidine gluconate 4% solution	Antiseptic

Uses

- surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
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- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use

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- in contact with meninges
- in the genital area

When using this product

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Drug Facts (continued)

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Other information

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Inactive ingredients: cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, triethyl alcohol

Questions or comments?
call 1-800-587-3721 Monday through Friday 8:00 AM to 4:30 PM CST

NDC 0116-2994-01

REF 29900-401

BD Scrub Care™

Exidine™-4 CHG 4%

Chlorhexidine Gluconate

4% Solution

Antiseptic

Contains:

4% Chlorhexidine Gluconate

For External Use Only

Distributed by

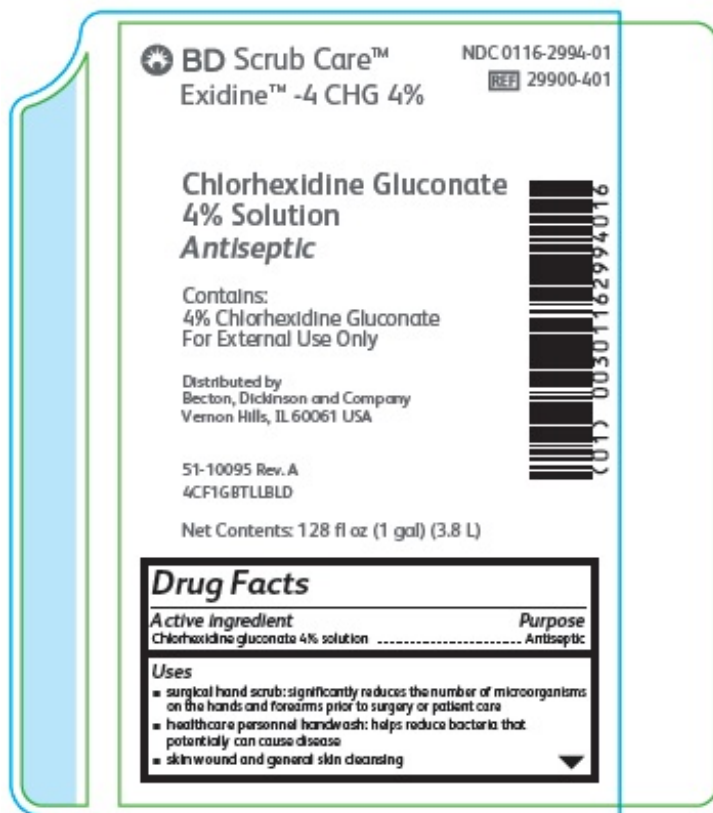
Becton, Dickinson and Company

Vernon Hills, IL 60061 USA

51-10095 Rev. A

4CF1GBTLLBLD

Net Contents: 128 fl oz (1 gal) (3.8 L)



SCRUB CARE EXIDINE -4 CHG

chlorhexidine gluconate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0116-2994
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0K00R)	
TRIDECYL ALCOHOL (UNII: 8I9428H868)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-2994-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2012	
2	NDC:0116-2994-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2012	
3	NDC:0116-2994-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2012	
4	NDC:0116-2994-17	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2012	
5	NDC:0116-2994-32	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2012	
6	NDC:0116-2994-33	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2012	
7	NDC:0116-2994-01	3786 mL in 1 JUG; Type 0: Not a Combination Product	11/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019125	11/01/2012	

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-2994)

Revised: 6/2020

Xttrium Laboratories, Inc.