

COVID-19 Information

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DEVICE: McKesson (00612479170315)

DEVICE IDENTIFIER (DI) INFORMATION

<u>Brand Name:</u> McKesson <u>Version or Model:</u> 102-S60C

Commercial Distribution Status: In Commercial Distribution

Catalog Number:

Company Name: MCKESSON MEDICAL-SURGICAL INC. Device Description: SYRINGE 60 CC LUER LOCK Sterile

Primary DI Number: 00612479170315

Issuing Agency: GS1

Commercial Distribution End Date:

Device Count: 25

<u>Labeler D-U-N-S® Number*:</u> 023904428 *<u>Terms of Use</u>

DEVICE CHARACTERISTICS

What MRI safety information does the labeling contain?	Labeling does not contain MRI Safety Information
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437):	No
Device labeled as "Not made with natural rubber latex":	Yes
For Single-Use:	Yes
Prescription Use (Rx):	Yes
Over the Counter (OTC):	No
<u>Kit:</u>	No
Combination Product:	No
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P):	No

GMDN

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GMDN Preferred Term Name	GMDN Definition
Oral/enteral syringe, single-use	A manual device intended to be used for the administration of oral medication or delivery of enteral nutrition by connection to an enteral administration device. It consists of a calibrated hollow barrel (cylinder) and a moveable plunger intended to be operated by a healthcare provider or parent device. The tip is designed to mate only with enteral administration devices and is incompatible with Luer connectors; the device may be colour-coded to distinguish it from syringes designed to mate with infusion/injection devices. It may include appropriate accessories (e.g., cap, bottle adaptor). This is a single-use device.

FDA PRODUCT CODE

Product Code	Product Code Name
KYZ	Syringe, Irrigating (Non Dental)

FDA PREMARKET SUBMISSION

FDA Premarket Submission Number	Supplement Number
Premarket Submission Number Not Available/Not Released	

Device Exempt from Premarket Submission: Yes

STERILIZATION

<u>Device Packaged as Sterile:</u> Yes <u>Requires Sterilization Prior to Use:</u> No

Sterilization Method

No Sterilization Methods Found

STORAGE AND HANDLING

Storage and Handling	
No storage/handling found	

CLINICALLY RELEVANT SIZE

Size Type Text	
No Device Sizes	

DEVICE RECORD STATUS

Public Device Record Key: 02b9b193-6e30-465e-8d76-4352e50e24e2

Public Version Date: January 22, 2020

Public Version Number: 2

DI Record Publish Date: November 08, 2019

ALTERNATIVE AND ADDITIONAL IDENTIFIERS ADDITIONAL IDENTIFIERS

PACKAGE DI

Package DI	Quantity per	Contains DI	Package Discontinue	Package Status	Package
Number	Package	Package	Date		Type
0061247917032 2	4	00612479170315		In Commercial Distribution	Case

SECONDARY DI

Issuing Agency	Secondary DI Number
No Secondary DIs found	

UNIT OF USE DI

Unit of Use DI Number: 00612479170308

DIRECT MARKING (DM)

Device Subject to Direct Marking (DM), but Excepted: No

DM DI Different from Primary DI: No

DM DI Number: None

PRODUCTION IDENTIFIER(S) IN UDI

Lot or Batch Number: Yes Serial Number: No Expiration Date: Yes Manufacturing Date: No

Donation Identification Number: No

CUSTOMER CONTACT

No Customer Contact currently defined