

DECLARATION OF CONFORMITY

Name and Address of Product Owner:

Cardinal Health 200 LLC
3651 Birchwood Drive, Waukegan
IL 60085
USA

We hereby declare that the below-mentioned devices have been classified according to the classification rules and Medical Devices regulations in Vietnam at the time of submission.

Manufacturing Site:

Covidien
Calle 9 Sur 1113 Ciudad Industrial 22444 Tijuana, Baja California Mexico

Medical Device(s):

<i>Product Name</i>	<i>Product Code</i>
Argyle Trocar Catheter Sharp Tip 8 Fr/Ch (2.7 mm) x 9" (23 cm)	8888560805
Argyle Trocar Catheter Sharp Tip 12 Fr/Ch (4.0 mm) x 9" (23 cm)	8888561027
Argyle Trocar Catheter Sharp Tip 24 Fr/Ch (8.0 mm) x 15-3/4" (40 cm)	8888561050
Argyle Trocar Catheter Sharp Tip 28 Fr/Ch (9.3 mm) x 15-3/4" (40 cm)	8888561068
Argyle Trocar Catheter Sharp Tip 10 Fr/Ch (3.3 mm) x 9" (23 cm)	8888561019
Argyle Trocar Catheter Sharp Tip 16 Fr/Ch (5.3 mm) x 9-8/10" (25 cm)	8888561035
Argyle Trocar Catheter Sharp Tip 20 Fr/Ch (6.7 mm) x 15-3/4" (40 cm)	8888561043
Argyle Trocar Catheter Sharp Tip 32 Fr/Ch (10.7 mm) x 15-3/4" (40 cm)	8888561076

Risk Classification:

Class B, Rule 7, Part II, Appendix I

Quality Management System Certificate:

Certification Body: TUV SUD

Certificate No: Q6 074735 0069 Rev.01

Issuance Date: 2022-05-11

Expiry Date: 2024-12-10

Standards Applied:

Standards Number	Standards Title
EN 556-1:2001/AC:2006	Sterilization Of Medical Devices - Requirements for Medical Devices to Be Designated "Sterile" - Part 1: Requirements for Terminally Sterilized Medical Devices
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
ISO 594-1:1986	Conical Fittings with A 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – General Requirements
ISO 7864:1993	Sterile Hypodermic Needles for Single Use
ISO 7886-1:1993	Sterile Hypodermic Syringes for Single Use –Syringes for Manual Use
ISO 9626	Stainless Steel Needle Tubing for The Manufacture of Medical Devices
ISO 11135-1:2007	Sterilization of Health Care Products - Ethylene Oxide - Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
EN ISO 111371:2006/A1:2013	Sterilization of Health Care Products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
EN ISO 11607-1: 2006	Packaging for Terminally Sterilized Medical Devices -- Part 1: Requirements for materials, Sterile Barrier Systems and Packaging Systems.
EN 1041:2008	Information Supplied by the Manufacturer with Medical Devices
EN ISO 11607-2: 2006	Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
ISO 10993-1:2009	ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ISO 10993-7	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
EN ISO 13485:2012	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
EN ISO 15223-1:2012	Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements

This declaration of conformity is valid from <13 May 2022>

Authorised Signatory:

C. Tanakasemsub

C.Tanakasemsub (May 17, 2022 14:07 GMT+8)

Chadaporn Tanakasemsub

Head of QA Commercial & Regulatory Affairs – APAC



May 17, 2022

Date





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Final Audit Report

2022-05-17

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