



**European Declaration of Conformity
to the Medical Device Regulations, (EU) 2017/745**

Manufacturer:	<i>Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, Utah 84095 USA SRN US-MF-000001366</i>
EU Representative:	<i>Merit Medical Ireland, Ltd. Parkmore Business Park West Galway, Ireland SRN IE-AR-000001011</i>
Product Name(s) / Trade Name(s):	Prelude® Roadster Sheath Introducer
Product Codes / Catalogue Numbers:	For Catalog Number listing and associated unit UDI-DI refer to electronically generated Oracle CE Mark Report
Intended Purpose:	The Prelude Roadster Guide Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.
Indication For Use:	The Prelude Roadster Guide Sheath Introducer is indicated to be used for the introduction of interventional and diagnostic devices into the peripheral (and coronary) vasculature.
Basic UDI-DI:	0884450BUDI386QA
Classification/Rule:	Class III; Rule 7 according to Annex VIII of the MDR
Conformity/Assessment Route:	Article 52 (6) Annex IX
Common Specifications to Which Conformity is Declared:	None



We declare that the above-mentioned product(s) meet the provisions of the Medical Device Regulations (EU) 2017/745. All supporting documentation is retained at the premises of the manufacturer. This declaration is issued under the sole responsibility of the manufacturer.

Notified Body: BSI Netherlands
Notified Body Number 2797

Annex IX Chapter I & III Certificate(s): MDR 716389
Date of first issue: 2021-05-27

Annex IX Chapter II Certificate(s): MDR 778246
Date of first issue: 2024-05-03

Signature: 
Glenn Norton
Vice President, Regulatory Affairs
For, and on behalf of, Merit Medical Systems, Inc.

Date: 4-Oct-2024

Place of Issue: 1600 West Merit Parkway
South Jordan, UT USA

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Final Audit Report

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