



# EU DECLARATION OF CONFORMITY

We, TERUMO CORPORATION  
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan  
with Single Registration Number: JP-MF-000017478

being the manufacturer of:

**Glidesheath Slender**

[ARTERIAL INTRODUCTION SETS]

**Intended purpose:**

The device is intended to be inserted percutaneously into the radial artery to facilitate the insertion of angiographic, electrode, balloon, or similar catheters.

**Basic UDI-DI:**

498735026IKSSQ

**Related product codes: See Appendix A (full list of active codes)**

declare that the above product of **Class IIa** is in conformity with the applicable requirements of the Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 52.6 of the Regulation, relating to the “Conformity assessment based on a quality management system and on assessment of technical documentation” set out in Annex IX, and by certification of Annex IX Chapter I & III (EU quality management system certificate number HZ 1485480-1), under the supervision of TÜV Rheinland LGA Products GmbH as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

There is no reference to Common Specifications that have been used to within the conformity assessment for Regulation (EU) 2017/745.

Authorised Representative: TERUMO EUROPE N.V.

Authorised Address: INTERLEUVENLAAN 40, 3001 LEUVEN, BELGIUM

with Single Registration Number:BE-AR-000001433

This EU declaration of conformity is issued under our sole responsibility.

Tokyo, 2024-01-22

(place and date of issue)

DocuSigned by:  
[Signature]  
Signer Name: Toshio Nakashima  
Signing Reason: I approve this document  
Signing Time: 2024-01-22 | 11:55:13 午前 JST  
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Toshio Nakashima  
General Manager  
Quality Assurance Department  
For and on behalf of  
TERUMO CORPORATION



**Appendix A – Related product codes**

Product code	UDI-DI (TERUMO CORPORATION Ashitaka Factory)	UDI-DI (TERUMO VIETNAM CO.,LTD.)
RM*ES5J10SQ	04987350722386	08935221225449
RM*ES5F16SQR	04987350722485	08935221225456
RM*RS5C10PQ	04987350722584	08935221225463
RM*ES5J16HQS	04987350723260	08935221225470
RM*RS5F10PQ	04987350722546	08935221225487
RM*ES5F10SQR	04987350722461	08935221225494
RM*ES5J16SQ	04987350722409	08935221225500
RM*ES5J10PQ	04987350722423	08935221225517
RM*ES5J16PQ	04987350722447	08935221225524
RM*RS5J10PQ	04987350722508	08935221225531
RM*RS5J16PQ	04987350722522	08935221225548
RM*RS5F16PQ	04987350722560	08935221225555
RM*ES6J10HQS	04987350715500	08935221225562
RM*ES6J16HQS	04987350715524	08935221225579
RM*ES6F10HQ	04987350715548	08935221225586
RM*ES6F16HQ	04987350715562	08935221225593
RM*ES6J10SQ	04987350716248	08935221225609
RM*ES6J16SQ	04987350716262	08935221225616
RM*ES6J10PQ	04987350716286	08935221225623
RM*ES6J16PQ	04987350716309	08935221225630
RM*ES6F10SQ	04987350716323	08935221225647
RM*ES6F16SQ	04987350716347	08935221225654
RM*ES6F10SQR	04987350716408	08935221225661
RM*ES6F16SQR	04987350716422	08935221225678
RM*ES6F10HQR	04987350716446	08935221225685
RM*ES6F16HQR	04987350716460	08935221225692
RM*RS6J10PQ	04987350715586	08935221225692
RM*RS6J16PQ	04987350715609	08935221225708
RM*RS6F10PQ	04987350715623	08935221225715
RM*RS6F16PQ	04987350715647	08935221225722
RM*RS6C10PQ	04987350726025	08935221225739



Rev. 00  
DoC No. DOC- DC-0061157  
Reference to. DC-0061157

Product code	UDI-DI (TERUMO CORPORATION Ashitaka Factory)	UDI-DI (TERUMO VIETNAM CO.,LTD.)
RM*ES7J10SQ	04987350722843	08935221225746
RM*ES7F16SQR	04987350722942	08935221225753
RM*RS7J10PQ	04987350722966	08935221225760
RM*RS7J16PQ	04987350722980	08935221225777
RM*ES7J10HQS	04987350726049	08935221225784
RM*ES7J16HQS	04987350723284	08935221225791
RM*RS7F10PQ	04987350723000	08935221225807
RM*ES7F10SQR	04987350722928	08935221225814
RM*ES7J16SQ	04987350722867	08935221225821
RM*ES7J10PQ	04987350722881	08935221225838
RM*ES7J16PQ	04987350722904	08935221225845
RM*RS7F16PQ	04987350723024	08935221225852