

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.** **CE 597867**  
Issued To: **Terumo Corporation**  
**44-1, 2-chome**  
**Hatagaya**  
**Shibuya-ku**  
**Tokyo**  
**151-0072**  
**Japan**

In respect of:

**Finecross MG Coronary Micro-Guide Catheter**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2013-06-04**

Date: **2019-03-04**

Expiry Date: **2023-06-03**

...making excellence a habit.™

Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Design-Examination Certificate

## Supplementary Information to CE 597867

Issued To:

**Terumo Corporation**  
**44-1, 2-chome**  
**Hatagaya**  
**Shibuya-ku**  
**Tokyo**  
**151-0072**  
**Japan**

| Product Code | Effective Shaft Length |
|--------------|------------------------|
| NC-F863A     | 130cm                  |
| NC-F865A     | 150cm                  |

First Issued: **2013-06-04**Date: **2019-03-04**Expiry Date: **2023-06-03**

...making excellence a habit.™

Page 2 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Design-Examination Certificate

## Supplementary Information to CE 597867

Issued To:

**Terumo Corporation**  
**44-1, 2-chome**  
**Hatagaya**  
**Shibuya-ku**  
**Tokyo**  
**151-0072**  
**Japan**

## Certificate History

| Date             | Reference Number | Action   |
|------------------|------------------|--|
| 4 June 2013      | 10141189         | First issue. Transfer from another Notified Body.  |
| 16 March 2016    | 10159714         | Change affecting Tyvek ®1073 B and Tyvek® 1059B packaging materials- all product codes are affected. |
| 31 May 2018      | 8896075          | Certificate renewal.   |
| 09 November 2018 | 8873289          | Using an additional sterilization chamber as part of the existing sterilization facility (Ashitaka). |
| Current          | 7778938          | Traceable to NB 0086.  |

First Issued: **2013-06-04**

Date: **2019-03-04**

Expiry Date: **2023-06-03**

...making excellence a habit.™

Page 3 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.