# DECLARATION OF CONFORMITY

We, **TERUMO EUROPE N.V.**
**Interleuvenlaan 40,**
**3001 Leuven, Belgium**

being the manufacturer of:

## SURFLO®-X I.V. CATHETER

**Product:** **Short Peripheral I.V. Catheter of FEP**
**Surflo®-S Plus (straight)**
**Surflo®-W (winged)**
**Surflo®-WP (winged and ported)**
**(See Appendix A for related product codes)**

declare that the above product of Class IIa is in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993 as amended, concerning medical devices, and has been subject to the conformity assessment procedure laid down in Article 11.2 and 11.2(b) of the Directive, relating to the procedure set out in Annex VII and Annex V, Production Quality Assurance, and by certification of Annex V.3, under the supervision of TÜV Rheinland LGA Products GmbH (Registration No: DD 60134712 0001), as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Leuven, 28 April 2020
(place and date of issue)

M.J. Aerts
VP Regulatory & Vigilance
TERUMO EUROPE N.V.

## Appendix A – Related product codes

The product code is composed of 11 digits and explained as follows:

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
|---|---|---|---|---|---|---|---|---|---|---|
| **S** | **R** | I.V. catheter | | | | | | | | |
| **Legal manufacturer** | | **+** | Terumo Europe N.V. | | | | | | | |
| **Surflo Wing** | | | **D** | **M** | FEP catheter | | | | | |
| **Catheter size (outer diameter)** | | | | | **1** | **4** | 14 G (= 2.00 mm) | | | |
| | | | | | **1** | **6** | 16 G (= 1.75 mm) | | | |
| | | | | | **1** | **7** | 17 G (= 1.50 mm) | | | |
| | | | | | **1** | **8** | 18 G (= 1.30 mm) | | | |
| | | | | | **2** | **0** | 20 G (= 1.00 mm) | | | |
| | | | | | **2** | **2** | 22 G (= 0.90 mm) | | | |
| | | | | | **2** | **4** | 24 G (= 0.74 mm) | | | |
| | | | | | **2** | **6** | 26 G (= 0.64 mm) | | | |
| **Catheter length** | | | | | | | **1** | **9** | 19 mm | |
| | | | | | | | **2** | **5** | 25 mm | |
| | | | | | | | **3** | **2** | 32 mm | |
| | | | | | | | **4** | **5** | 45 mm | |
| **Type** | | | | | | | | | **S** | Straight |
| | | | | | | | | | **W** | Wing only |
| | | | | | | | | | **P** | Wing and injection port |
| **Radiopaque** | | | | | | | | | | **X** |