

### EC DECLARATION OF CONFORMITY

We Poly Medicure Limited, Plot No. 104-105 & 115-116, Sector-59, HSIIDC Industrial Area, Ballabgarh - 121004, Faridabad, INDIA.

Hereby declare and take responsibility to ensure that the following product:

• **UNILINE**

| S. No. | Product Description                                           | Medical Device Class | Polymed Reference Code | Asept Reference Code |
|--------|---------------------------------------------------------------|----------------------|------------------------|----------------------|
| 1      | PVC Extension Line 3 X 4.1 X 500mm                            | IIa                  | 1012L.05               | 202094               |
| 2      | PVC Extension Line 3 X 4.1 X 1000mm                           | IIa                  | 1012L.10               | 202095               |
| 3      | PVC Extension Line 3 X 4.1 X 1500mm                           | IIa                  | 1012L.15               | 202096               |
| 4      | PVC Extension Line 3 X 4.1 X 2000mm                           | IIa                  | 1012L.20               | 202097               |
| 5      | PVC Extension Line 1.5 X 3 X 500mm                            | IIa                  | 1012H.05               | 202098               |
| 6      | PVC Extension Line 1.5 X 3 X 1000mm                           | IIa                  | 1012H.10               | 202099               |
| 7      | PVC Extension Line 1.5 X 3 X 1500mm                           | IIa                  | 1012H.15               | 202100               |
| 8      | PVC Extension Line 1.5 X 3 X 2000mm                           | IIa                  | 1012H.20               | 202101               |
| 9      | PE Extension Line 3 X 4.1 X 500mm                             | IIa                  | 1032.25                | 202102               |
| 10     | PE Extension Line 3 X 4.1 X 1000mm                            | IIa                  | 1032.3                 | 202103               |
| 11     | PE Extension Line 3 X 4.1 X 1500mm                            | IIa                  | 1032.35                | 202104               |
| 12     | PE Extension Line 3 X 4.1 X 2000mm                            | IIa                  | 1032.4                 | 202105               |
| 13     | PE Extension Line 1 X 2 X 500mm with male rotating luer lock  | IIa                  | 1032.05                | 202106               |
| 14     | PE Extension Line 1 X 2 X 1000mm with male rotating luer lock | IIa                  | 1032.1                 | 202107               |
| 15     | PE Extension Line 1 X 2 X 1500mm with male rotating luer lock | IIa                  | 1032.15                | 202108               |
| 16     | PE Extension Line 1 X 2 X 2000mm with male rotating luer lock | IIa                  | 1032.2                 | 202109               |
| 17     | PVC Extension Line 3 X 4.1 X 100mm luer lock                  | IIa                  | 1012L.01               | 202127               |
| 18     | PVC Extension Line 1.5 X 3 X 300mm                            | IIa                  | 1012H.03               | 202130               |
| 19     | PE Extension Line 1 X 2 X 100mm with male rotating luer lock  | IIa                  | 1032.01                | 202131               |
| 20     | PE Extension Line 1 X 2 X 300mm with male rotating luer lock  | IIa                  | 1032.03                | 202132               |
| 21     | PVC Extension Line 3 X 4.1 X 300mm lock                       | IIa                  | 1012L.03               | 202128               |
| 22     | PVC Extension Line 1.5 X 3 X 100mm                            | IIa                  | 1012H.01               | 202129               |

As per Annexure – IX of the Medical Device Directive comply with the product standards/ requirements and, meet the essential requirements according to Annexure- I of the Council Directive 93/42/EEC of 14<sup>th</sup> June 1993 as amended by 2007/47/EC concerning medical devices.

Conformity Assessment Procedure was carried out according to Annexure - II excluding section 4 (Module – H) of the MDD and is certified by the following Notified Body.

Name, Address & No.

: TÜV SÜD Product Service GmbH,  
Ridlerstraße 65, 80339, Munich, Germany  
Notified Body Number 0123,

CE Certificate No.

: G1 041938 0007

European Authorized Representative Address

: OBELIS S.A.  
Boulevard Général Wahis 53,  
B-1030, Brussels, Belgium,  
mail@obelis.net



Ramdas Sharma  
DGM - Quality

On behalf of POLY MEDICURE LTD. Faridabad