

## EU Declaration of Conformity to MDD

| PRODUCT IDENTIFICATION                         |              |
|------------------------------------------------|--------------|
| Product name: Silicone Vessel Loops            | Model/number |
| 16" Mini Red, Non-Sterile, 100/bag             | 011001BBG    |
| 16" Mini Red, Non-Sterile, 1000/bag            | 011001BBI    |
| 16" Mini Red, Non-Sterile, 2/pouch, 100/bag    | 011001NBG    |
| 16" Mini Red, Sterile                          | 011001PBX    |
| 16" Mini Blue, Non-Sterile, 100/bag            | 011002BBG    |
| 16" Mini Blue, Non-Sterile, 1000/bag           | 011002BBI    |
| 16" Mini Blue, Non-Sterile, 2/pouch, 100/bag   | 011002NBG    |
| 16" Mini Blue, Sterile                         | 011002PBX    |
| 16" Mini Yellow, Non-Sterile, 100/bag          | 011003BBG    |
| 16" Mini Yellow, Non-Sterile, 1000/bag         | 011003BBI    |
| 16" Mini Yellow, Non-Sterile, 2/pouch, 100/bag | 011003NBG    |
| 16" Mini Yellow, Sterile                       | 011003PBX    |
| 16" Mini White, Non-Sterile, 100/bag           | 011004BBG    |
| 16" Mini White, Non-Sterile, 1000/bag          | 011004BBI    |
| 16" Mini White, Non-Sterile, 2/pouch, 100/bag  | 011004NBG    |
| 16" Mini White, Sterile                        | 011004PBX    |
| 16" Maxi Red, Non-Sterile, 100/bag             | 011011BBG    |
| 16" Maxi Red, Non-Sterile, 1000/bag            | 011011BBI    |
| 16" Maxi Red, Non-Sterile, 2/pouch, 100/bag    | 011011NBG    |
| 16" Maxi Red, Sterile                          | 011011PBX    |
| 16" Maxi Blue, Non-Sterile, 100/bag            | 011012BBG    |
| 16" Maxi Blue, Non-Sterile, 1000/bag           | 011012BBI    |
| 16" Maxi Blue, Non-Sterile, 2/pouch, 100/bag   | 011012NBG    |
| 16" Maxi Blue, Sterile                         | 011012PBX    |
| 16" Maxi Yellow, Non-Sterile, 100/bag          | 011013BBG    |
| 16" Maxi Yellow, Non-Sterile, 1000/bag         | 011013BBI    |
| 16" Maxi Yellow, Non-Sterile, 2/pouch, 100/bag | 011013NBG    |
| 16" Maxi Yellow, Sterile                       | 011013PBX    |
| 16" Maxi White, Non-Sterile, 100/bag           | 011014BBG    |
| 16" Maxi White, Non-Sterile, 1000/bag          | 011014BBI    |
| 16" Maxi White, Non-Sterile, 2/pouch, 100/bag  | 011014NBG    |
| 16" Maxi White, Sterile                        | 011014PBX    |
| 22" Supermaxi White, Sterile                   | 011021PBX    |
| 22" Supermaxi Blue, Non-Sterile, 100/bag       | 011022BBG    |
| 22" Supermaxi Blue, Sterile                    | 011022PBX    |
| 22" Micro Blue, Sterile                        | 011032PBX    |
| 30" Mini Red, Sterile                          | 011301PBX    |
| 30" Mini Blue, Sterile                         | 011302PBX    |
| 30" Mini Yellow, Sterile                       | 011303PBX    |
| 30" Mini White, Sterile                        | 011304PBX    |

|                                               |           |
|-----------------------------------------------|-----------|
| 30" Maxi Red, Sterile                         | 011311PBX |
| 30" Maxi Blue, Sterile                        | 011312PBX |
| 30" Maxi Yellow, Sterile                      | 011313PBX |
| 30" Maxi White, Sterile                       | 011314PBX |
| 18" Mini Red, Non-Sterile, 2/card, 100/bag    | 016001BBG |
| 18" Mini Blue, Non-Sterile, 2/card, 100/bag   | 016002BBG |
| 18" Mini Yellow, Non-Sterile, 2/card, 100/bag | 016003BBG |
| Mini Blue, Sterile                            | 2400-1BCE |
| Mini Red, Sterile                             | 2400-1RCE |
| Mini White, Sterile                           | 2400-1WCE |
| Mini Yellow, Sterile                          | 2400-1YCE |
| Maxi Blue, Sterile                            | 2400-2BCE |
| Maxi Red, Sterile                             | 2400-2RCE |
| Maxi White, Sterile                           | 2400-2WCE |
| Maxi Yellow, Sterile                          | 2400-2YCE |
| Mini Blue, Non-Sterile                        | 2800-1BCE |
| Mini Red, Non-Sterile                         | 2800-1RCE |
| Mini White, Non-Sterile                       | 2800-1WCE |
| Mini Yellow, Non-Sterile                      | 2800-1YCE |
| Maxi Blue, Non-Sterile                        | 2800-2BCE |
| Maxi Red, Non-Sterile                         | 2800-2RCE |
| Maxi White, Non-Sterile                       | 2800-2WCE |
| Maxi Yellow, Non-Sterile                      | 2800-2YCE |

| MANUFACTURER                  |                                                             |                |
|-------------------------------|-------------------------------------------------------------|----------------|
| Name of company               | Address                                                     | Representative |
| Aspen Surgical Products, Inc. | 6945 Southbelt Drive SE<br>Caledonia, Michigan 49316<br>USA | Kerry Turner   |

| AUTHORIZED REPRESENTATIVE |                                                            |                                                |
|---------------------------|------------------------------------------------------------|------------------------------------------------|
| Name of company           | Address                                                    | Telephone/email                                |
| Emergo Europe             | Prinsessegracht 20<br>2514 AP The Hague<br>The Netherlands | +31.70.345.8570 - phone<br>EmergoEurope@ul.com |

| NOTIFIED BODY                                                                                                  |                       |
|----------------------------------------------------------------------------------------------------------------|-----------------------|
| Notified Body and ID #                                                                                         | CE certificate number |
| BSI<br>Say Building, John M. Keynesplein 9<br>1066 EP Amsterdam, The Netherlands<br>Notified Body Number: 2797 | CE 612363             |

| CONFORMITY ASSESSMENT |                                                |                   |
|-----------------------|------------------------------------------------|-------------------|
| Device classification | Route to compliance                            | Standards applied |
| Class IIa<br>Rule 7   | Annex II of MDD 93/42/EEC<br>Council Directive | ISO 13485: 2016   |

Aspen Surgical Products Inc. declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Stephanie Sullivan

**TITLE:** Senior Regulatory Affairs Specialist **SIGNATURE:**

**DATE:** May 20, 2021