

Nous / We:

Spengler S.A.S.  
30 rue Jean de Guiramand  
13290 Aix-en-Provence  
France

SRN : **FR-MF-000041197**

Déclarons sous notre entière responsabilité que les dispositifs médicaux suivants :

*Declare under our sole responsibility that the following medical devices:*

**« Brassards de garrot »**

**« Tourniquet cuffs »**

IUD-ID de base des Brassards de garrot :

*Basic UDI-DI of Cuffs Tourniquet :*

**37004682BCGRX**

Destination :

**Le garrot permet d'obtenir un champ opératoire exsangue en facilitant ainsi le geste chirurgical et raccourcissant le temps opératoire.**

*Destination :*

*The tourniquet makes it possible to obtain a bloodless operating field, facilitating the surgical procedure and shortening the operating time.*

Code GMDN : **17230**

Appartenant à la classe I en application de la règle 1 du chapitre II de l'annexe VIII du Règlement (UE) 2017/745

*Belonging to class I according to Rule 1 of chapter III from Annex VIII of the regulation 2017/745*

Sont conformes aux exigences applicables du Règlement 2017/745 et de sa transposition dans le Code de la Santé Publique Français.

*Are in conformity with the relevant Community harmonization legislation: Regulation 2017/745 and its transposition into the French Public Health Code.*

Cette déclaration est basée sur les éléments suivants :

*This declaration is based on the following:*

- Dossier technique Brassards GAE démontrant la conformité aux exigences générales en matière de sécurité et performances du Règlement 2017/745

*Technical file Brassards GAE demonstrating compliance with the general safety and performance requirements of the Regulation 2017/745*

- Certificat NF EN ISO 13485 : 2016 n° 16589 relatif au système de management de la qualité, délivré par l'organisme notifié GMED (0459)

*Certificate of registration NF EN ISO 13485: 2016 number 16589 concerning the quality management system, issued by the notified body GMED (0459)*

La présente déclaration concerne tous les dispositifs listés dans le tableau en Annexe 1.

*This declaration applies to all medical devices listed in the table in Annex 1.*

Pour attester de cette conformité, le marquage CE a été apposé sur les produits en Annexe 1.

*To certify this conformity, the marking CE has been affixed to the products listed in the table in Annex 1.*

Fait à Aix-en-Provence, le 13 juin 2025

*Issued in Aix-en-Provence on June 13, 2025*

Lucie CASSARD

Directrice Qualité/Affaires Réglementaires

SPENGLER SAS  
30, rue Jean de Guiramaud  
13290 AIX-EN-PROVENCE  
Tel 04 42 52 89 89 Fax 04 42 52 89 09  
Siret : 41866673900081

|                                                                                 |                                                                            |                                          |
|---------------------------------------------------------------------------------|----------------------------------------------------------------------------|------------------------------------------|
|  | <b>Déclaration CE de conformité</b><br><i>EC Declaration of conformity</i> | Ref : QR-DC-Brassards<br>Garrot_13062025 |
|---------------------------------------------------------------------------------|----------------------------------------------------------------------------|------------------------------------------|

## Annexe 1 / Annex 1

### Brassards et cuissards monoblocs

| Référence | Désignation FR                                               | Designation EN                                                     |
|-----------|--------------------------------------------------------------|--------------------------------------------------------------------|
| GBDM101   | Brassard garrot monobloc droit nourrisson -3.5x29cm DDM      | Straight monoblock arm cuff new born -3.5x29cm DDM                 |
| GBDM102   | Brassard garrot monobloc droit enfant -4.5x35cm DDM          | Straight monoblock arm cuff child - 4.5x35cm DDM                   |
| GBDM103   | Brassard garrot monobloc droit petit adulte -6x46cm DDM      | Straight monoblock arm cuff small adult -6x46cm DDM                |
| GBDM104   | Brassard garrot monobloc droit adulte -8x46cm DDM            | Straight monoblock arm cuff adult -8x46cm DDM                      |
| GBCM105   | Brassard garrot monobloc conique adulte L -10x47cm DDM       | Conical monoblock arm cuff adult L -10x47cm DDM                    |
| GCDM103   | Cuissard garrot monobloc droit petit adulte -8x76cm DDM      | Conical monoblock lower limb cuff small adult -8x76cm DDM          |
| GCDM104   | Cuissard garrot monobloc droit adulte -10x62cm DDM           | Straight monoblock lower limb cuff adult -10x62cm DDM              |
| GCDM105   | Cuissard garrot monobloc droit adulte L -10x76cm DDM         | Straight monoblock lower limb cuff adult L -10x76cm DDM            |
| GCDM106   | Cuissard garrot monobloc droit adulte XL -10x82cm DDM        | Straight monoblock lower limb cuff adult XL -10x82cm DDM           |
| GCDM107   | Cuissard garrot monobloc droit adulte XXL -10x107cm DDM      | Straight monoblock lower limb cuff adult XXL -10x107cm DDM         |
| GCCM104   | Cuissard garrot monobloc conique adulte -10x62cm DDM         | Conical monoblock lower limb cuff adult -10x62cm DDM               |
| GCCM105   | Cuissard garrot monobloc conique adulte L -10x76cm DDM       | Conical monoblock lower limb cuff adult L -10x76cm DDM             |
| GCCM106   | Cuissard garrot monobloc conique adulte XL -10x82cm DDM      | Conical monoblock lower limb cuff adult XL -10x82cm DDM            |
| GCCM107   | Cuissard garrot monobloc conique adulte XXL -10x107cm DDM    | Conical monoblock lower limb cuff adult XXL -10x107cm DDM          |
| GBDM204   | Brassard garrot monobloc droit 2 poches adulte -6x46cm DDM   | Two bladders straight monoblock arm cuff adult -6x46cm DDM         |
| GBDM202   | Brassard garrot monobloc droit 2 poches enfant -4.5x35cm DDM | Two bladders straight monoblock arm cuff child - 4.5x35cm DDM      |
| GCCM204   | Cuissard garrot monobloc droit 2 poches adulte -7x62cm DDM   | Two bladders straight monoblock lower limb cuff adult - 7x62cm DDM |

### Brassards et cuissards monoblocs avec sangle

| Référence | Désignation FR                                                      | Designation EN                                                      |
|-----------|---------------------------------------------------------------------|---------------------------------------------------------------------|
| GBDMS101  | Brassard garrot monobloc droit nourrisson -3.5x29cm DDM sangle      | Straight monoblock arm cuff new born -3.5x29cm DDM buckle           |
| GBDMS102  | Brassard garrot monobloc droit enfant -4.5x35cm DDM sangle          | Straight monoblock arm cuff child - 4.5x35cm DDM buckle             |
| GBDMS103  | Brassard garrot monobloc droit petit adulte -6x46cm DDM sangle      | Straight monoblock arm cuff small adult -6x46cm DDM buckle          |
| GBDMS104  | Brassard garrot monobloc droit adulte -8x46cm DDM sangle            | Straight monoblock arm cuff adult -8x46cm DDM buckle                |
| GBCM105   | Brassard garrot monobloc conique adulte L -10x47cm DDM sangle       | Conical monoblock arm cuff adult L -10x47cm DDM buckle              |
| GCDMS103  | Cuissard garrot monobloc droit petit adulte -8x76cm DDM sangle      | Conical monoblock lower limb cuff small adult -8x76cm DDM buckle    |
| GCDMS104  | Cuissard garrot monobloc droit adulte -10x62cm DDM sangle           | Straight monoblock lower limb cuff adult -10x62cm DDM buckle        |
| GCDMS105  | Cuissard garrot monobloc droit adulte L -10x76cm DDM sangle         | Straight monoblock lower limb cuff adult L -10x76cm DDM buckle      |
| GCDMS106  | Cuissard garrot monobloc droit adulte XL -10x82cm DDM sangle        | Straight monoblock lower limb cuff adult XL -10x82cm DDM buckle     |
| GCDMS107  | Cuissard garrot monobloc droit adulte XXL -10x107cm DDM sangle      | Straight monoblock lower limb cuff adult XXL -10x107cm DDM buckle   |
| GCCMS104  | Cuissard garrot monobloc conique adulte -10x62cm DDM sangle         | Conical monoblock lower limb cuff adult -10x62cm DDM buckle         |
| GCCMS105  | Cuissard garrot monobloc conique adulte L -10x76cm DDM sangle       | Conical monoblock lower limb cuff adult L -10x76cm DDM buckle       |
| GCCMS106  | Cuissard garrot monobloc conique adulte XL -10x82cm DDM sangle      | Conical monoblock lower limb cuff adult XL -10x82cm DDM buckle      |
| GCCMS107  | Cuissard garrot monobloc conique adulte XXL -10x107cm DDM sangle    | Conical monoblock lower limb cuff adult XXL -10x107cm DDM buckle    |
| GBDMS204  | Brassard garrot monobloc droit 2 poches adulte -6x46cm DDM sangle   | Two bladders straight monoblock arm cuff adult -6x46cm DDM buckle   |
| GBDMS202  | Brassard garrot monobloc droit 2 poches enfant -4.5x35cm DDM sangle | Two bladders straight monoblock arm cuff child -4.5x35cm DDM buckle |

|                 |                                                                            |                                          |
|-----------------|----------------------------------------------------------------------------|------------------------------------------|
| <b>SPENGLER</b> | <b>Déclaration CE de conformité</b><br><i>EC Declaration of conformity</i> | Ref : QR-DC-Brassards<br>Garrot_13062025 |
|-----------------|----------------------------------------------------------------------------|------------------------------------------|

|          |                                                                      |                                                                         |
|----------|----------------------------------------------------------------------|-------------------------------------------------------------------------|
| GCCMS204 | Cuissard garrot monobloc droit 2 poches adulte -7x62cm DDM<br>sangle | Two bladders straight mono. lower limb cuff adult -7x62cm<br>DDM buckle |
|----------|----------------------------------------------------------------------|-------------------------------------------------------------------------|

### **Brassards et cuissards autoclavables**

| <b>Référence</b> | <b>Désignation FR</b>                                                 | <b><i>Designation EN</i></b>                                           |
|------------------|-----------------------------------------------------------------------|------------------------------------------------------------------------|
| GBS101           | Brassard/Cuissard garrot autoclavable droit nourrisson - 4x19cm       | Straight autoclavable cuff new born -4x29cm DDM                        |
| GBS102           | Brassard garrot autoclavable droit enfant -5x26.5cm DDM               | Straight autoclavable arm cuff child -5x26.5cm DDM                     |
| GCS102           | Cuissard garrot autoclavable droit enfant -6x35.5cm DDM               | Straight autoclavable lower limb cuff child -6x35.5cm DDM              |
| GBS103           | Brassard garrot autoclavable droit petit adulte -6x35.5cm DDM         | Straight autoclavable arm cuff small adult -6x35.5cm DDM               |
| GCS103           | Cuissard garrot autoclavable droit petit adulte -6x53cm DDM           | Straight autoclavable lower limb cuff small adult -6x53cm DDM          |
| GBS104           | Brassard garrot autoclavable droit adulte -6x53cm DDM                 | Straight autoclavable arm cuff adult -6x53cm DDM                       |
| GCS104           | Cuissard garrot autoclavable droit adulte -9x69cm DDM                 | Straight autoclavable lower limb cuff adult -9x69cm DDM                |
| GCS105           | Cuissard garrot autoclavable droit adulte L -9x81cm DDM               | Straight autoclavable lower limb cuff adult L -9x 81 cm DDM            |
| GCS106           | Cuissard garrot autoclavable droit adulte XL -12x85.5cm DDM           | Straight autoclavable lower limb cuff adult XL -12x85.5cm DDM          |
| GBS202           | Brassard garrot autoclav. droit 2 poches enf./petit ad.- 6x35.5cm DDM | Two bladders straight autoclav. arm cuff child/small ad.- 6x35.5cm DDM |
| GBS204           | Brassard garrot autoclavable droit 2 poches adulte -6x53cm DDM        | Two bladders straight autoclavable arm cuff adult - 6x53cm DDM         |
| GCS204           | Cuissard garrot autoclavable droit 2 poches adulte -9x69cm DDM        | Two bladders straight autoclavable lower limb cuff adult - 9x69cm DDM  |
| GCCS104          | Cuissard garrot autoclavable conique adulte -9x69cm DDM               | Conical autoclavable lower limb cuff adult -9x69cm DDM                 |
| GCCS105          | Cuissard garrot autoclavable conique adulte L -9x81cm DDM             | Conical autoclavable lower limb cuff adult L -9x81cm DDM               |
| GCCS106          | Cuissard garrot autoclavable conique adulte XL -12x85.5cm DDM         | Conical autoclavable lower limb cuff adult XL -12x85.5cm DDM           |