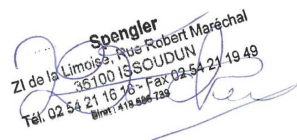


DÉCLARATION DE CONFORMITÉ A LA DIRECTIVE 93/42/CEE  
CONFORMITY ASSESSMENT BASED ON DIRECTIVE 93/42/EEC

|                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer                                  | Spengler S.A.S                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Adresse du fabricant<br>Place of manufacturer | ZI La Limoise - Rue Robert Maréchal<br>36100 Issoudun - FRANCE                                                                                                                                                                                                                                                                                                                                                                                            |
| Produit<br>Product                            | Stéthoscope<br>Stethoscope                                                                                                                                                                                                                                                                                                                                                                                                                                |
| GMDN code                                     | 13755                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Classification                                | Classe I (Règle 1) - Class I (Rule 1)                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Modèle<br>Model                               | Dual Pulse<br>Dual Pulse                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Références<br>Reference                       | 507400 - Dual Pulse Noir<br>Dual Pulse Black<br>507421 - Dual Pulse Bleu Azur<br>Dual Pulse Sky blue<br>507422 - Dual Pulse Bleu Marine<br>Dual Pulse Navy blue<br>507423 - Dual Pulse Rose bougainvillier<br>Dual Pulse Pink bougainvillea<br>507424 - Dual Pulse Gris<br>Dual Pulse Grey<br>507427 - Dual Pulse Carmin<br>Dual Pulse Carmine<br>507428 - Dual Pulse Vert lagon<br>Dual Pulse Green lagon<br>507430 - Dual Pulse Rouge<br>Dual Pulse Red |
| Référentiel de conformité                     | Directive Européenne relative aux dispositifs médicaux 93/42/CEE, Annexe VII,<br>Déclaration CE de conformité                                                                                                                                                                                                                                                                                                                                             |
| Conformity<br>assessment route                | Medical Device Directive 93/42/EEC, Annex VII, EC Declaration of<br>conformity                                                                                                                                                                                                                                                                                                                                                                            |
| Normes appliqués<br>Applied<br>Standards      | BS EN ISO 15223-1 :2012, EN 1041 :2008, EN ISO 14971 :2012                                                                                                                                                                                                                                                                                                                                                                                                |
| Organisme Notifié<br>Notified Body            | Non applicable<br>Not applicable                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Numéro du Certificat<br>EC Certificate No     | Non applicable<br>Not applicable                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Valable jusqu'au<br>Valid Until               | 10 Juillet 2018<br>July 10th 2018                                                                                                                                                                                                                                                                                                                                                                                                                         |

Le fabricant certifie que le(s) produit(s) mentionné(s) ci-dessus répondent aux dispositions de la Directive 93/42/CEE du Conseil en vue (Annexe VII, Déclaration CE de conformité).

We herewith that the above-mentioned product(s) meet the provisions of council Directive for 93/42/EEC (Annex VII, EC Declaration of conformity)



Spengler  
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ISSOUDUN, FRANCE, le 17 Nov 2016  
Lieu et date  
Place and date of issue

Laurent VACHTER  
Responsable Délégué au Marquage CE  
Delegate Manager in charge of the CE marking