

## DECLARATION OF CONFORMITY

**This declaration is issued under the sole responsibility of the manufacturer.**

|                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| COMPANY ADDRESS                     | <b>PVS Spa</b><br>LEGALE SITE: Via Leonardo da Vinci, 18 - 20051 Cassina de' Pecchi (MI)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Unique registration number (art.31) | not available yet                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| DEVICE                              | FOLDABLE STRETCHER                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| DESCRIPTION                         | FOLDABLE STRETCHER                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| PVS CODE                            | BAR016                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| BUDI-DI (UDI-DI di base)            | 80340280124f                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| INTENDED USE                        | device for transport of the injured person.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| RISK CLASS                          | I (Rule, 1 - Annex VIII)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| CONFORMITY ASSESSMENT PROCEDURE     | Annex II (technical documentation)<br>Annex III (technical documentation on post-market surveillance)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| DECLARATION                         | <p>It declares under its own responsibility:</p> <ul style="list-style-type: none"> <li>• that the device meets the general safety and performance requirements set out in Annex I of EU regulation 2017/745 on medical devices and the applicable technical standards set out in the technical file.</li> <li>• that the device in question IS NOT A MEASURING INSTRUMENT;</li> <li>• that the device in question is sold in NO STERILE packaging;</li> <li>• that the devices in question are not intended for clinical investigations;</li> <li>• that the company has implemented and maintains a post-marketing surveillance procedure, in accordance with the requirements of Annex III;</li> <li>• that the device is produced and marketed by applying the company Quality System certified according to the UNI EN ISO 9001: 2015 standard;</li> <li>• that the company undertakes to keep and make available to the Competent Authority the technical documentation, specified in Annex II and III for a period of at least 10 years from the last date of manufacture of the product;</li> <li>• that the device in question complies with the requirements of EU regulation 2017/745 and that it is placed on the market with the CE marking, in accordance with the provisions of Article 20.</li> </ul> |

### PVS SpA

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Reg.imprese MI n. 215184  
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Cassina De Pecchi, 11/01/2022

IRENE PEREGO  
GENERAL MANAGER



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