

## DECLARATION OF CONFORMITY

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

COMPANY ADDRESS	<b>PVS Spa</b> LEGALE SITE: Via Leonardo da Vinci, 18 - 20051 Cassina de' Pecchi (MI)
Unique registration number (art.31)	not available yet
DEVICE	STAIR CHAIR 2 OR 4 WHEELS
DESCRIPTION	STAIR CHAIR 2 OR 4 WHEELS
PVS CODE	SED001 – SED004
BUDI-DI (UDI-DI di base)	80340280124F
INTENDED USE	device for the transport of patients in a sitting position from the place of intervention to the ambulance or other device intended for transport on the medical vehicle.
RISK CLASS	I (Rule, 1 - Annex VIII)
CONFORMITY ASSESSMENT PROCEDURE	Annex II (technical documentation) 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;               <ul style="list-style-type: none"> <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> </li> </ul>

### PVS SpA

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 cap.soc. Euro 619.748,28 i.v.  
 Reg.imprese MI n. 215184  
 R.E.A. MI n. 1103165

Cassina De Pecchi, 08/09/2021

IRENE PEREGO  
GENERAL MANAGER






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