



## 2. EU DECLARATION OF CONFORMITY

### The manufacturer:

Company: Givas S.r.l.

Address: Viale Veneto, 2 Z.A. - 35020 Villatora di Saonara (PD) - Italy

### Declares, under its own and exclusive responsibility, that the device(s)

Code	Model	ID BD/RDM	UDI-DI
MR5278	Relax Patient transfer Armchair Vario Free Plus - electric armchair on wheels	1122368/R	-
MR1278	Relax Patient transfer Armchair Vario Free Plus - electric armchair on wheels	1278994/R	-
AP1185	"Prelievi New Vario" Armchair	1665505/R	-

Intended purpose: AP1185: the device is intended to be used in patient's diagnosis, treatment and monitoring.  
 MR5278 - MR1278: the device is intended to be used in patient's diagnosis, treatment and monitoring; it can also be used for the for the transfer and the stationing of a patient, in closed rooms, with the assistance of an operator.  
 Usage environment: within welfare and health facilities.  
 Product to be used by: patients, specialised operators and doctors.  
 Supervision and responsibility: the chair must be used under a doctor's supervision.

Risk class: Class I

### It complies with the following Union legislative acts:

8	2017/745/EU	Regulation (EU) 2017/745 of the european Parliament and of the Council, of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
	2006/42/EC	Directive 2006/42/EC of the european Parliament and of the Council, of 17 May 2006 on machinery, and amending Directive 95/16/EC
	2014/35/EU	Directive 2014/35/EU of the european Parliament and of the Council, of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits
	2014/30/EU	Directive 2014/30/EU of the european Parliament and of the Council, of 17 May 2006 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility
	2011/65/EU	Directive 2011/65/EU of the european Parliament and of the Council, of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

### It complies with the following harmonized standards and/or common specifications:

CEI EN 60601-1:2007 Medical electrical equipment  
 Part 1: General requirements for basic safety and essential performance

The device is associated with the evaluation procedure provided for by article 52, point 7 of Regulation 2017/745/EU

Saonara,  
 4<sup>th</sup> may 2020

Chairman of the Board of Directors  
 Berto Silvio