



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	Basic UDI-DI
MR1068	Free Plus Relax Patient transfer Armchair	1275549/R	-
ZMR10682	Free Plus Relax Patient transfer Armchair with centralized brake	1275578/R	-
MR1065	Free Relax Patient transfer Armchair	1275582/R	-
ZMR10651	Free Basic Relax Armchair	1926919/R	-
MR1066	Syncro Plus Relax Patient transfer Armchair	1275585/R	-
MR1062	Syncro Basic Relax Armchair	1275592/R	-
MR1063	Syncro Relax Patient transfer Armchair	1275598/R	-
MR1078	Vario Free Plus Relax Patient transfer Armchair	1275634/R	-
MR1076	Vario Syncro Plus Relax Patient transfer Armchair	1275642/R	-

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Intended purpose: The device is intended to be used exclusively as an armchair, for the transfer (apart from mod. MR1062 - ZMR10651) 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:

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

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

Saonara,
4th may 2020

Chairman of the Board of Directors
Berto Silvio