



2. DECLARATION OF CONFORMITY EU

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
AP1160	Blood donor armchair	1514527/R	805253040AP1160Q9
AP1164	Blood donor armchair with independent movements	1514531/R	805253040AP1164QH

Intended purpose: The device is intended to be used exclusively as an armchair in the treatment of a patient.
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.
The armchair cannot be used in a potentially explosive atmosphere.

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

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

Saonara,
April 12, 2021

Chairman of the Board of
Directors
Berto Silvio

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