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
AP4010	Gynecological examination chair	477222/R	-
AP4012	Urological examination chair	477295/R	-

Intended purpose: The device is intended to be used in adult patient's diagnosis, treatment and monitoring, under a doctor's supervision.
Usage environment: within welfare and health facilities.
The chair cannot be used in potentially explosive or inflammable atmosphere.
People authorised to use the product: patient, specialised operators and doctors.

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

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,
5th october 2020

Chairman of the Board of Directors
Berto Silvio