

	EU CONFORMITY DECLARATION	V.03
		07/2021

Manufacturer address:

VIA ACTUAL – Comércio Internacional, Lda
Centro Empresarial Castelo da Maia,
Rua Manuel Assunção Falcão, nº. 337
4475-041 Santa Maria de Avioso

Infarmed: Nr **154/DM/2016**, de 22 September 2016

Eudamed: SRN APP000002876

Product(s) Description(s):

REF ^a	Description	UDI-DI
H22R3	THERAPY CHAIR SERIE II, 3 MOTORS	 5 600670 936101
H22R4	THERAPY CHAIR SERIE II, 4 MOTORS	 5 600670 936118
H23E3	THERAPY CHAIR ECO SERIE II	 5 600670 936125
C41Q3	SAMPLING CHAIR SERIE IV 3 MOTORS	 5 600670 936132
C61Q0	SAMPLING CHAIR SERIE VI WITH GAS SPRING SYSTEM	 5 600670 936149
G71G4	GYNAECOLOGICAL CHAIR SERIE VII	 5 600670 936156

The issuer of this declaration of conformity is responsibility for the manufacture. The purpose of the declaration referred to above, is in conformity with the relevant harmonization legislation of the European Union.



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Low Voltage Directive 2014/35 / EU

Directive 2014/35 / EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the availability on the market of electrical equipment designed for use within certain voltage limits.

EMC Directive 2014/30 / EU

Directive 2014/30 / EU of the European Parliament and of the Council. Of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility.

The above standards comply with Directive 2011/65/EU of the European Parliament and 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 essential requirements set out in **Regulation (EU) 2017/745 of 05th April** a Class I Active Medical Device and therefore does not endanger the health and safety of patients / for the purpose for which it was designed.

UNDERTAKES:

- Keep at the disposal of the competent authority (INFARMED, IP) the documentation showing the place of manufacture and to understand the design, manufacture, and the functional performance of the product, including the expected operation level, in order to allow for the assessment of its conformity with the requirements of Regulation (EU) 2017/745 of 05th April.
- To take all measures necessary in order that the manufacturing process ensures compliance of the manufactured products with the documentation.
- Keep updated for a minimum period of 5 years, all relevant information concerning the device including the present Declaration.
- To make the Declaration of conformity in order to keep up with the medical device in accordance with Regulation (EU) 2017/745 of 05th April.
- Analyze and document experience gained in the post-production phase, including the provisions referred to Annex III of Regulation (EU) 2017/745 of 05th April and to develop appropriate means to apply any necessary corrective action, commitment that includes the obligation to inform the competent Authority (INFARMED, IP), about the incidents, so that one has knowledge, such as:
 - Any malfunction, failure or deterioration in the characteristics or performances, and any inaccuracy, omission or insufficient in the labelling or the instructions for use of a device, which are likely to cause or have caused death or serious deterioration in the State of health of a patient, user or third;
 - Any indirect damage following an incorrect medical decision related to a medical device, when used in accordance with the instructions for use provided by the manufacturer;

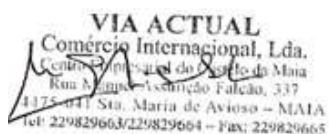


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- Any technical or medical reason, characteristic or related with the performance of a device for the reasons referred to in paragraph above, has led to corrective action on the Portuguese market of devices of the same type by the manufacturer;
- Other information that experiences shows to be notified.

Maia, 30th July 2021

MANUFACTURER SIGNATURE


VIA ACTUAL
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 Centro Empresarial do Oeste da Maia
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(Elisabete Almeida - Manager)

