EU DECLARATION OF CONFORMITY

CE

the manufacturer

TRIRIDE SRL

Declares under its sole responsibility that the medical devices for the motorization of wheelchairs for disabled people comply with all applicable provisions of Regulation (EU) 2017/745 and the related harmonized standards:

EN 12182:2012;
EN 12183:2022;
EN 12184:2022;
ISO 7176-9:2009;
ISO 7176-14:2008;
ISO 7176-15:1996;
ISO 7176-21:2009;
EN60601-1:2006/A1:2013/A12:2014/A2:2021;
EN 60601-1-2:2015/A1:2021;
EN 60601-1-6:2010/A1:2015/A2:2021;
EN ISO 14971:2019/A11:2021;
EN ISO 15223-1:2021;
EN ISO 20417:2021;
EN 62366-1:2015/AC:2015/A1:2020;
EN 62304:2006/A1:2015;
EN ISO 10993-1:2020;
EN ISO 13485:2016/AC:2018/A11:2021.

They also comply with all applicable provisions of 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 and Commission Delegated Directive 2015/863 of 31 March 2015 amending Annex II of Directive 2011/65/EU.
To this end, it is declared that the devices in question meet the essential requirements of Annex I of Regulation (EU) 2017/745, as per Annexes II and III of the Regulation.

The devices in question, according to rule 13, are to be considered as belonging to class I.