

## CONFORMITY DECLARATION ACCORDING TO ANNEX VII, 93/42/EEC DIRECTIVE

**ORMESA S.r.l.** guarantees and declares , under its own exclusive responsibility, that the following Medical Device, technical aid for rehabilitation:

### **MINI-STANDY sizes 1/2/3** **STANDING FRAME FOR AN UPRIGHT POSITION**

which this declaration refers to, is manufactured by Ormesa srl in conformity with the general requirements provided in the Directive **93/42/EEC** and subsequent amendments and additions, concerning the medical devices, according to which this aid belongs to the **I risk class** and has been **designed in observance to the following standards:**

CEI EN ISO 14971:2012	Medical Devices - Application of risk management to medical
UNI EN 12182:2012	technical aids for disabled persons - general requirements and test methods
UNI CEI EN 15223-1:2012	Symbols for use in the medical device labels, labeling and information to be supplied - Part 1: General requirements
EN 1041:2013	Information supplied by the manufacture with medical devices
ISO 9999:2011	Technical aids for persons with disabilities - Classification and terminology

August 31st, 2016

The Legal Representative  
Luigi Menichini