

CONFORMITY DECLARATION

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

MINI STANDY DJ

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**:

DIRETTIVA 2014/30/UE	Harmonization of the Member States relating to electromagnetic compatibility
UNI CEI EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
UNI EN 12182:2012	Products designed to assist people with disabilities - General requirements and test methods
ISO 9999:2011	Technical aids for disabled persons - Classification
UNI EN 1041:2013	Information supplied by the manufacturer with medical devices
UNI CEI EN ISO 15223-1:2012	Symbols for use in the medical device labels, labeling and information to be supplied - Part 1: General requirements
CEI EN 60601-1-2:2010	General requirements for basic safety and essential performance. Collateral standard. Prescription electromagnetic compatibility and tests.
CEI EN 61000-3-2:2007	(EMC) Limits for harmonic current emissions
CEI EN 61000-3-3:2014	(EMC) Limits for voltage fluctuations of voltage fluctuations flicker in low voltage supply systems for equipment with rated current ≤ 16A
CEI EN 61000-4-4:2013	(EMC) immunity test transients, bursts of pulses fast Electric
CEI EN 61000-4-2:2011	(EMC) immunity test static electricity discharge
CEI EN 61000-4-11:2006	(EMC) immunity test voltage dips, short interruptions and voltage variations
CEI EN 61000-4-3:2007	(EMC) Immunity to radio frequency electromagnetic fields radiated
CEI EN 61000-4-5:2007	(EMC) immunity test pulse
CEI EN 61000-4-6:2011	(EMC) Testing and measurement techniques - Immunity to conducted disturbances, induced by RF fields
CEI EN 55011:2013	Industrial, scientific and medical. radio disturbance characteristics. Limits and methods of measurement
CEI EN 60335-1	Safety of household and similar electrical appliances di'uso. General rules

Foligno, 25.10.2016

Il Legale Rappresentante
Luigi Menichini

