

DECLARATION OF CONFORMITY



The manufacturer Gardhen Balance S.r.l.
con sede unica in via Giuseppe Luraghi
c/o Consorzio il sole - lotto s
80038 Pomigliano d'Arco (NA)

DECLARES THAT THE PRODUCT

**STEPHEN H FLAT - STEPHEN H ECO - STEPHEN H ECO 2.0
STEPHEN H FREEDOM - STEPHEN H ANATOMICAL
STEPHEN H COMFORT 2.0 - STEPHEN H COMFORT 3.0
STEPHEN H COMFORT 4.0 - STEPHEN H COMFORT 5.0
ATHENA - ATHENA 2.0 - HOME CHAIR
GMDN CODE 38447**

This declaration of conformity is issued under the sole responsibility of the manufacturer pursuant to Annex IV of EU Regulation 2017/745. The aforementioned devices are manufactured in compliance with: EU Regulation 2017/745, relating to medical devices, annexes I and IX through the application of the CEI EN 60601-1 and CEI EN 60601-2-52 standards, the latter relating only to beds.

All the design and production phases meet the requirements indicated in the company Quality Management System in accordance with the provisions of Annex IX, Chapter I of the aforementioned Medical Device Regulation. This company Quality Management System complies with the requirements specified in the UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485: 2016 standards and is certified by IMQ S.p.A. (certificate n ° 9120.GARD and certificate n ° 9124.GAR2).

The devices are to be considered as belonging to class I.

THE PRESIDENT
MARIA PAUMGARDHEN