DECLARATION OF CONFORMITY

CE

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

DECLARES THAT THE PRODUCT

Examination couch with integrated scale

Model: Francis Scale A/V

CND/EMDN Code: V080603

GMDN CODE : 34870

This declaration of conformity is issued under the sole responsibility of the manufacturer (SRN IT-MF-000013019) pursuant to Annex IV of EU Regulation 2017/745.
The aforementioned devices are manufactured in compliance with:
EU Regulation 2017/745, related to medical devices, annex IX (certification n° 126/MDR, issued by the Notified Body IMQ S.p.A, through the application of the CEI EN 60601-1 and CEI EN 60601-2-52 standards, the latter being related only to beds, CEI EN 50637 related only to paediatric beds, these, although not yet harmonized in compliance with MDR 2017/745 UE represent the state of the art; - to the "Decreto Legislativo" December 29th – 1992 no.517 modified as per D. lgs n. 83 dated 19 May 2016, concerning the actuation of the directive 2014/31/UE , on non-automatic weighing instruments, (certificate N ° ATLab-I16-012/2 issued by the notified body 2081 Special Company of Chamber of Commerce of Asti through the application of the norm UNI CEI EN 45501).
Furthermore, the aforementioned devices are tally to the model described in the EU Certificate "del TIPO_ATLab-I22-032/0".
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 Regulation for Medical Devices.
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) and by ISO 14001:2015 certified by ICM (certificate 000002012). The serial UDI-DI change according to device's configuration. As provided under Annex VII, Chapter III of Regulation EU 2017/745 the devices are to be considered as belonging to **class IIa, in conformity with Rule 10.**

Date 20-06-2024

THE PRESIDENT

MARIA PAUMGARDHEN