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

Model: FRANCIS AV 3.0

BASIC UDI-DI: 805771740LVISKK

CND/EMDN Code: V080603

GMDN CODE : 34134

This EU 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 Gardhen Bilance S.r.l. (SRN IT-MF-000013019) in compliance with EU Regulation 2017/745, relating to medical devices, annexes II and III through the application of the CEI EN 60601-1 and CEI EN 60601-2-52 standards, the latter relating only to beds, CEI EN 60601-2-46 the latter relating only to surgical table. These norms although not yet harmonized according to MRD 2017/745 UE actually represent the state of art. 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) and by ISO 14001:2015 certified by ICM (certificate 2017_08_197/Q). The serial UD-DI changes according to the configuration of the device.

The devices are to be considered as belonging to risk's class I, in compliance with Annex VIII of EU Regulation 2017/745.

Date 09-11-2025

GARDHEN BILANCE S.r.l.
Il Legale Rappresentante

THE PRESIDENT
MARIA PAUMGARDHEN