DECLARATION OF CONFORMITY

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The manufacturer Gardhen Bilance 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

Type: Multifunctional electric chair

Model: ATHENA

GMDN Code: 38447

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer Gardhen Bilance S.r.l. (SRN IT-MF-000013019) in accordance with Annex IV of the EU Regulation 2017/745.

The above-mentioned devices are manufactured in accordance with: the EU Regulation 2017/745 on medical devices, Annexes II and III. The harmonised standards according to which the devices are manufactured are CEI EN 60601-1 and CEI EN 60601-2-52, the latter relating to beds only, CEI EN 60601-2-46 the latter relating to operating tables only, and these, despite not yet being harmonised according to EU MDR 2017/745 represent the state of the art.

All design and production phases meet the requirements of the company's Quality Management System in accordance with the provisions of Annex IX, Chapter I of the aforementioned Medical Devices 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 no. 9120.GARD and certificate no. 9124.GAR2) and by ISO 14001:2015 certified by ICM (certificate no. 000002012). The Serial UDI-DI varies depending on the device configuration.

As defined by Annex VII, Chapter III of EU Regulation 2017/745, the devices are to be considered as belonging to risk **class I**, in accordance with Rule 1.

Pomigliano d'Arco (NA) 09/05/2024**.**

THE PRESIDENT
MARIA PAUMGARDHEN