

DECLARATION OF CONFORMITY

Manufacture name:
GAMMA POLIURETANI SRL
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We hereby declare that under our sole responsibility that the medical device AURION POLYURETHANE MEDICAL CARTS AND ACCESSORIES describe hereafter meets the provisions of the Directives 93/42/EEC, which apply to this declaration, relates is in conformity with the following applied harmonized standard: -

UNI EN ISO 9001 : 2015
UNI CEI EN ISO 13485 : 2016

We hereby declare that:

1. The Medical device has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and conforms to requirements specified in APPENDIX 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices Regulations 2012
2. The Medical Device ARE NOT A MEASURING DEVICE
3. The Medical Device ARE NOT SUBJECT TO CLINICAL INVESTIGATIONS
4. The Medical Devices are LATEX FREE
5. The Medical Devices are sold in NON-STERILE packing
6. The Medical Devices do not include BATTERIES.
7. The Medical Devices have a manufacturing serial number.
8. The Medical Devices are not subject to any EXPIRING.

Medical Device Class 1
GMDN: 40542
HS CODE: 9402 9000
COUNTRY OF ORIGIN: ITALY



Michele Damo
RD/QA
GAMMA POLIURETANI SRL

14/01/2021

Product Family: HOSPITAL TROLLEY
Model: MINI600 (ISO BASKET TROLLEY) - REF. CODE: 27934

Registered number: 1699970
Repertory: N

CODE	DESCRIPTION
MS000X	AURION MINI 600 HOSPITAL TROLLEY - ISO BASKET AND TRAYS COMPARTMENT (EMPTY)
MS1200	TRANSPARENT DOORS WITH KEY LOCKING DEVICE


Michele Damo
RD/OA
GAMMA POLIURETANI SRL

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