

EC DECLARATION OF CONFORMITY
(Editorial No. 1 dd. 27.11.2023)

Manufacturer: **SUBSIDIARY ENRERPRISE COMPANY ZAPOVIT**
Address: Pivnichno-Syretska st, 3, Kyiv, Ukraine, 04136
Product: **MEDICAL FURNITURE**
Model: Assortment according to Annex No. 1
Classification: Class I, CHAPTER III, 4.1., Rule 1 REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Regulation (EU) MDR 2017/745)
Conformity: RINA Services S.p.A.
Assessment Route: Notified Body number: SGQ № 002 A
GMDN Code:

We herewith declare that the above mentioned products meet the provisions of the following Regulation (EU) MDR 2017/745).

DIRECTIVES

General Applicable Directive:

Medical Device Regulation: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices

ISO 15223-1:2016

ISO 14155:2020

ISO 10993-1:2018

ISO 13485:2016

ISO 14971:2019



Director
Potyrailo Olga

SUBSIDIARY ENRERPRISE COMPANY ZAPOVIT
Kyiv, Ukraine

27 November 2023

ANNEX No. 1
to the EC DECLARATION OF CONFORMITY
Editorial No. 1 dd. 27.11.2023

MEDICAL FURNITURE – TABLES

Manipulating table SM-3
Manipulating table SM-3E
Manipulating table SM-3-2
Side table SI-5
Instrumental table CP
Anesthesiologist table SA
Nurse table SMS
Table for storage VZ-5
Table for the hand SDR

MEDICAL FURNITURE – COUCHES

Procedural couch with adjustable head support KRP
Procedural couch KP
Massage couch KM
Massage couch with manual height adjustment KMR

MEDICAL FURNITURE – BEDS

Double-section functional bed KF-2M
Four-section functional bed KF-4M
Functional children bed KFD for children up to five years
Medical stationary functional bed KFM
Triple-section functional bed KF-3M
Four-section functional bed with manual adjustment KF-4 R1
Four-section functional bed with double manual adjustment KF-4 R2
Functional crib KFD-2

MEDICAL FURNITURE – TABLES

Three-section massage table M-3
Single-section massage table M-1

MEDICAL FURNITURE – CARTS

Cart for transportation of patients with removable stretchers TBS-150
Cart for transportation of patients with removable stretchers TBS-200
Cart for transportation of the patient with height adjustment TPBR
Cart for transportation of patients TPB

MEDICAL FURNITURE – CHAIRS

Sorption armchair VR
Gynecological armchair KG-1ME
Gynecological armchair KG-1M
Gynecological armchair KG-2M
Gynecological armchair KG-3R with manual adjustment

Director



Potyrailo Olga

SUBSIDIARY ENRERPRISE COMPANY ZAPOVIT
Kyiv, Ukraine

27 November 2023