



RUSSIA

Monitor Ltd

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Research & Production Company «Monitor» Ltd.

Is presented by the Authorized Representative in EC
CMC Medical Devices & Drugs S.L.
Address: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain

DECLARATION OF CONFORMITY

The undersigned, Yury Popov, general director of Research & Production Company
“Monitor” Ltd.,
Address: 104a Krasnokursantskaya Street, Rostov-on-Don, Russia
hereby declares that medical device

PATIENT MONITOR MITAR 01 RD

meets all requirements of Council Directives 93/42/EEC (MDD) and 2011/65/EC (RoHS).

MDD classification: IIb (Annex IX)

Standards Applied: IEC 60601-1:2012
IEC 60601-1-2:2014
IEC 80601-2-49:2018
IEC 60601-2-27:2011
IEC 80601-2-30:2018
ISO 80601-2-61:2017
ISO 80601-2-55:2018

This Declaration of Conformity is based on European Medical Device Directive 93/42/EEC Annex II and European Directive 2011/65/EU (RoHS).

Certificate No.: CE 543428 dated 03 Sept 2020

Certificate No.: MD 543429 dated 05 Feb 2019

Notified Body: The British Standards Institution
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands,
Notified Body Number 2797

Valid until: September 02, 2021

Signature

(Yury Popov)

Date: September 04, 2020