DECLARATION OF CONFORMITY NR.19/05/01

MANUFACTURER:

MedTeCo LTD. Russia, 141009

Mytishchi, Moscow region, Olympiysky prospect 16\2

EU REPRESENTATIVE:

Medical Devices Ltd

мед ТеКо

1149 Budapest Vezér str. 79/2 Hungary

PRODUCTS:

Bactericidial recirculator irradiator BRI 15 Bactericidial recirculator irradiator BRI 30

Serial Number from:

DECLARATION:

We herewith declare that the above mentioned products meet the provisions of the DIRECTIVE 2014/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED:

EN ISO 13485 EN ISO 14971

EN ISO 15223-1

EN 60601-1

EN 60601-1-2

EN 1041:2008

Mytishchi, 2019. 05. 01.

Alexandr Benkov