



Certifikat / Certificate

za
sistem menadžmenta

BODY BOOST BED DOO BEOGRAD-RAKOVICA

Brestovačka 10, 11090 Beograd - Rakovica

Proizvodnja i prodaja medicinskih sredstava za svetlosnu terapiju
na lokaciji 13. oktobra 42b, 11231 Beograd

*ima uspostavljen i održavan sistem menadžmenta,
koji ispunjava zahteve standarda*

ISO 13485:2016

Sertifikat broj / Datum sertifikacije

M-113 / 2017-06-28

Izdanje 03 / 2020-05-14 *Važi do:* 2023-06-28

Direktor SIQ Ljubljana

Igor Likar



**SLOVENSKA
AKREDITACIJA**
SIST EN ISO/IEC 17021-1
CS-001

SIQ Ljubljana, Mašera-Spasičeva ulica 10, 1000 Ljubljana, Slovenija



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

SIQ Ljubljana has issued an IQNet recognized certificate that the organization:

BODY BOOST BED DOO BEOGRAD-RAKOVICA

Brestovačka 10, 11090 Beograd - Rakovica, Serbia

*has implemented and maintains a Medical devices - Quality System
for the following scope:*

Production and sales of medical devices for light therapy
on site 13. oktobra 42b, 11231 Beograd

which fulfils the requirements of the following standard:
ISO 13485:2016

First issued on: **2017-06-28**

Issued on: **03 / 2020-05-14** *Expires on:* **2023-06-28**

*This attestation is directly linked to the IQNet Partner's original certificate
and shall not be used as a stand-alone document*

Registration Number: SI – M-113



Alex Stoichitoiu
President of IQNet

Igor Likar
Managing Director of SIQ Ljubljana



IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

Manufacturer: Body Boost Bed d.o.o. Trinaestog oktobra 42b, 11231 Belgrade-Rakovica, Serbia
SRN: RS-MF-000040919
Product Name: Body Boost Bed
Model/Type: BBB MED S9001
Classification: IIa (Annex IX, Rule 9)
GMDN Code: /
EU Authorised rep. International Associates Auditing & Certification Limited
The Black Church, St Mary's Place,
Dublin 7, D07 P4AX Ireland
EUAR@ie.ia-net.com

BODY BOOST BED d.o.o. HEREBY STATES THAT THE ABOVE MENTIONED PRODUCT(S) COMPLY WITH THE ESSENTIAL REQUIREMENTS OF THE COUNCIL DIRECTIVE 93/42/EEC, CONSOLIDATED AS PER 2007/47/EEC, FOR MEDICAL DEVICES.

The product was a subject of conformity assessment procedure described in Annex V (Production quality assurance).

Standards applied:

- EN ISO 13485:2016
- EN ISO 15223-1:2021
- EN 1041:2008 + A1:2013
- EN ISO 14971:2019
- EN ISO 10993-1:2020
- EN ISO 10993-5:2009
- EN ISO 10993-10:2013
- EN 60601-1:2006 + A1:2013+A12:2014 + AC:2014
- EN 60601-1-2:2015
- EN 60601-1-6:2010 + A1:2015
- EN 60601-2-57:2011
- EN 62366-1:2015+A1:2020
- EN 62471:2006
- EN 62304:2006 /A1:2015

Notified body: International Associates Auditing & Certification Limited
The Black Church, St Mary's Place,
Dublin 7, D07 P4AX Ireland
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EC Certificate: No: 1304-MDD-089
Certification date: 2018-03-01
Issue: 02/2021-03-12
Valid until: 2024-05-27
Extension validated until 2028-12-31 acc. to Ref.doc. Notified Body
Confirmation Letter No 5438-2024/01,date 2024-05-22

General manager