06 DECLARATIONS

06.01 Declaration of Conformity

EC DECLARATION of CONFORMITY

We, as ***Yalong Trade s.r.o.*** declare that our products manufactured in **Yalong Trade s.r.o.** with the addresses below:

Ruzova 728/2, 05001 Revuca, Slovakia (assembly & warehouse)
M.Bodickeho 1517/14, 05001 Revuca, Slovakia (headquarters)

with its model, classification according to 93/42/EEC Medical Devices Directive Annex IX, and GMDN code provided below, are manufactured in compliance with the below-mentioned standards and guidelines;

93/42/EEC Medical Devices Directive, Annex V Product Quality Assurance System,
EN ISO 60825–1: 2014, EN 62304:2006/A1:2015, EN 60601–1:2006/A1:2012, EN 60601-1-11: 2015, IEC 60601-1-2: 2014, EN ISO 10993-1:2018, EN 10993-5:2009, EN 10993-10:2013, ISO 10993-4:2017, ISO 10993-3:2014, ISO 1099311:2018.

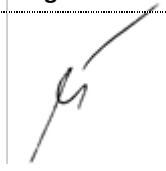
Product Name	Model Name	Class	Rule	GMDN/UMDNS Code
Semiconductor diode laser therapy device	BioQuant®NS	IIa	9	GMDN Code of the laser blood irradiation device BioQuant®NS is P57809 UMDNS code of the laser blood irradiation device BioQuant®NS is 28802

The conformity of our products with the directives and documents above are approved with the certificate whose information are provided below, by the notified body Kiwa Certification Services Inc., (Kiwa Belgelendirme Hizmetleri A.Ş.) Istanbul Tuzla Organize Sanayi Bölgesi Tepeören Mevkii Orhanlı 34957, Tepeören – Istanbul/ TURKEY, with the identification number 1984.

Certificate No	:	1984-MDD-17-438
Certificate First Issue Date	:	09.05.2017
Certificate Expiry Date	:	27.05.2024
Certificate Revision No	:	01
Certificate Revision Date	:	17.06.2019

Approved by	:	Viera Kokosova
Title	:	General Manager
Issue Date	:	30.5.2019
Issue Place	:	Revuca, Slovakia
Declaration Revision No	:	02
Declaration Revision Date	:	27.06.2019

Signature



06.02 Substance Declaration

SUBSTANCE DECLARATION

We, as ***Yalong Trade s.r.o.*** declare that our products manufactured in ***Yalong Trade s.r.o.*** with the addresses below:

Ruzova 728/2, 05001 Revuca, Slovakia (assembly & warehouse)
M.Bodickeho 1517/14, 05001 Revuca, Slovakia (headquarters)

with the information provided in the following table,

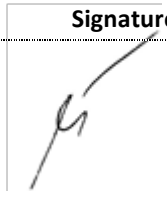
Product Name	Model Name	Class	Rule	GMDN/UMDNS Code
Semiconductor diode laser therapy device	BioQuant®NS	IIa	9	GMDN Code of the laser blood irradiation device BioQuant®NS, P57809; UMDNS Code, 28802

do not contain any;

- Medicinal products for human use, as identified in the directive 2001/83/EC article 1,
- Human blood derivatives referred to in Section 7.4 of Annex I of Directive 93/42/EEC as amended by Directive 2007/47/EC,
- Tissues of animal origin referred to in Directive 722/2012/EC,
- Phtalates as referred to in the directive 1272/2008/EHS,
- PFOS (perfluoroctansulfonates) as identified in the directive 2006/122/EC.

Approved by	:	Viera Kokosova
Title	:	General Manager
Issue Date	:	27.06.2019
Issue Place	:	Revuca, Slovakia

Signature



06.03 Declaration of Company Quality System and Its Continuity

Declaration of Company Quality System and Its Continuity

We, as ***Yalong Trade s.r.o.*** declare that our products manufactured in **Yalong Trade s.r.o.** with the addresses below:

Ruzova 728/2, 05001 Revuca, Slovakia (assembly & warehouse)
M.Bodickeho 1517/14, 05001 Revuca, Slovakia (headquarters)

with its model, classification according to 93/42/EEC Medical Devices Directive Annex IX, and GMDN code are provided below, are manufactured in compliance with the following standards and guidelines;

93/42/EEC Medical Devices Directive, Annex V Product Quality Assurance System,
EN ISO 60825–1: 2014, EN 62304:2006/A1:2015, EN 60601–1:2006/A1:2012, EN 60601-1-11: 2015, IEC 60601-1-2: 2014, EN ISO 10993-1:2018, EN 10993-5:2009, EN 10993-10:2013, ISO 10993-4:2017, ISO 10993-3:2014, ISO 1099311:2018.

We declare that all requirements of the quality system of the product which is produced in accordance with above mentioned standards and guidelines will be fulfilled, quality system will be continued completely and effectively, a system is established for the purpose of reviewing the data which is obtained from production and this system will be updated, the required corrective actions are performed like which is indicated in 93/42/EEC Medical Devices Directive-Annex X and defined in PR.20 Technical File Preparation Procedure.

Product Name	Model Name	Class	Rule	GMDN/UMDNS Code
Semiconductor diode laser therapy device	BioQuant®NS	IIa	9	GMDN Code of the laser blood irradiation device BioQuant®NS is P57809 UMDNS code of the laser blood irradiation device BioQuant®NS is 28802

The conformity of our products with the directives and documents above are approved with the certificate whose information are provided below, by the notified body Kiwa Certification Services Inc., (Kiwa Belgelendirme Hizmetleri A.Ş.) Istanbul Tuzla Organize Sanayi Bölgesi Tepeören Mevkii Orhanlı 34957, Tepeören – Istanbul/ TURKEY, with the identification number 1984.

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Title	:	General Manager
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Issue Place	:	Revuca, Slovakia
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Signature