Slovenská obchodná a priemyselná komora

MANUFACTURE AND FREE SALE

CERTIFICATE No.: 023/2024

TO WHOM IT MAY CONCERN

UNDERSIGNED AUTHORITY,

SLOVENSKÁ OBCHODNÁ A PRIEMYSELNÁ KOMORA - SOPK

SLOVAK CHAMBER OF COMMERCE AND INDUSTRY - SCCI,

Grösslingová 4, 816 03 Bratislava, Slovak Republic,

a public legal institution established according to the Law No. 9/1992 Coll. as amended and revised, and on the basis of submitted documents

HEREBY CERTIFIES THAT:

1. A company **Chirana Progress, s.r.o.** (further only MANUFACTURER), with the seat in Vrbovská cesta 17, Piešťany, Postal code 921 01, Slovak Republic (SK), ID No.: 36 224 626, is a Limited liability company established under the laws of the Slovak Republic on 13 November1997 and registered in the Business Register of the District Court Trnava, Section: Sro, Insert No 10672/T, with the subject matter: manufacture, repair of medical devices and instruments and medical supplies.
2. MANUFACTURER has its Manufacturing plant in Piešťany (SK) which has been granted authorisation (license), No. 2516/2019-3, for manufacturing of the of physiotherapy devices under the Act no. 355/2007 Coll., as amended, by the Regional Public Health Office in Trnava, on 1998. Medical Devices (hereinafter referred as "MDs") made in the Manufacturing plant are registered in accordance with the Act no. 362/2011 Coll. with the State Institute for Drug Control (SIDC) - the Competent Authority for Medicine and MDs in the Slovak Republic, EU.
3. MDs made in the above Manufacturing plant, which are listed in the Annex of the M&FSC, comply with the requirements and standards for the safety of Medical Devices as required by applicable legislation of the Slovak Republic and the European Union, i.e.:
   - Act no. 56/2018 Coll. on conformity assessment of product, making the product available on the market and amending certain laws;
   - Act no. 362/2011 Coll. on medicines and medical devices and on amendments to certain laws, as amended;
   - Regulation (EU) 2017/745 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, as amended;
   - Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS);
4. MANUFACTURER is the holder of: (i) the EC Certificate no. 2018-MDD/QS-007 (valid ad interim based on Notified Body Confirmation Letter ref.: LUL/2023/P001 dtd 11 May 2023) of Full Quality Assurance System MDs according to Annex II, excluding (4) of MDD 93/42/EEC as amended; (ii) the Conformity Certificate no.M-0102/21 (valid until to 25 March, 2024) according with EN ISO 13485:2016 and (iii) the Certificate no. Q-0161/21 (valid until to 25 March 2024) of the Quality management system for design, development, production, purchase, sale, installation and service of active (non-implantable) medical hydrotherapeutic and electrometrical device according with ISO 9001:2015 , all of them issued by 3EC International a.s., Bratislava (SK) (EU Notified Body No. 2265; resp. Reg. No. 305/Q-050), accredited by SNAS, Bratislava (SK).
5. MANUFACTURER has prepared technical documentation, issued EC Declaration of Conformity (EC DoC) and affixed the CE mark with the MDs specified in the Annex II according to the MDD no. 93/42/EEC, as amended, therefore the MDs maybe freely sold in all member states of the European Union including the Slovak Republic. Export of the MDs outside EU is not prohibited.
6. This Certificate of Manufacture & Free Sale is issued to the Manufacturer on its request.

Bratislava, 29 February 2024	SLOVENSKÁ OBCHODNÁ A PRIEMYSELNÁ KOMORA SLOVAK CHAMBER OF COMMERCE AND INDUSTRY -01-	Jela Bieliková
Place and Date of Issue	Certification Seal	Name, signature of competent officer of SCCI

MANUFACTURE AND FREE SALE CERTIFICATE No. 023/2024

continue

Annex to M&FSC:

LIST OF MEDICAL DEVICES

Chirana Progress, s.r.o., Piešťany, Slovakia

(MANUFACTURER)

Item:	Product Name / Models, type	MD Reg. no./ SIDC	MD Class	EU Declaration of conformity no./ Date of issue
I.	**HYDROTHERAPY EQUIPMENT:**			
1	• Laguna, Laguna Plus, Laguna Bubble, Laguna Plus Bubble	P22650	II. a	EC DoC (SRN code: SK-MF-000016090) issued by Manufacturer on 21 March 2023
2	• Laguna Tornado	P22654		
3	• Ocean Economy, Ocean Standard ,Ocean Forte	P22654		
4	• Ocean de Luxe	P22653		
5	• Cascade, Cascade Plus, Cascade de Luxe	P22653		
6	• Cascade Senior	P26217		
7	• Lastura	P26218		
8	• Lastura Profi	P26217		
9	• Lastura Hobby	P22562		
10	• Coral, Coral Economy	P22562		
11	• Coral Lymfo	P26215		
12	• Hubbard Bath, Hubbard Bath Plus	P26215		
13	• VOD 56, VOD 56 HT	P26216		
14	• Niagara, Niagara Plus	P28886		
15	• Electra, Electra CG	P10403		
II.	**THERMOTHERAPY EQUIPMENT:**			EC DoC (SRN code: SK-MF-000016090) issued by Manufacturer on 21 March 2023
16	• TEP	P28471	I.	
III.	**CHAIRS:**			
17	• M1, M2, M3,	P22565	I.	
IV.	**MASSAGE TABLES:**			
18	• VOD 47	P28483	I.	
V.	**ACCESSORIES:**			
19	• BUBBLE GRID	P28482	I.	
20	• CIRCULAR SHOWER	P22566	I.	
21	• SITZ SHOWER	P22567	I.	

Note:
SIDC - the State Institute for Drug Control in Bratislava, SK,
EU DoC - EC Declaration of Conformity;