Slovak Chamber of Commerce and Industry

CERTIFICATE OF FREE SALE

No. 302553

TO WHOM IT MAY CONCERN

UNDERSIGNED AUTHORITY, **SLOVENSKÁ OBCHODNÁ A PRIEMYSELNÁ KOMORA**
(SLOVAK CHAMBER OF COMMERCE AND INDUSTRY, SCCI),
a public legal institution from 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.** (Ltd.), **/further only Manufacturer/,** headquartered on address: 17, Vrbovská cesta, **PIEŠŤANY**, Postcode 921 01, **Slovak Republic**, the company established under the laws of the Slovak Republic and registered in the Business Register of the District Court Trnava since January 20, 1998, Section: **Sro, Insert No. 10672/T,** with the subject matters: **manufacturing, repairing, distribution and sale of medical devices** (MD), **instruments and medical supplies,** i.e. active (no implantable) medical hydrotherapeutic and electro medical devices.
2. **The Manufacturer** has its **Manufacturing plant in Piešťany** (SK). **Products made in the above Manufacturing plant, which are listed in the Annex, meet all the requirements and standards for the safety of medical devices (MDs) as required by applicable legislation of the Slovak Republic and the European union, i.e.:**
   - **Act no. 362/2011 Coll.** on medicines and medical devices and on amendments to certain laws, as amended;
   - **Act no. 264/1999 Coll.** on Technical Requirements for Products and on Conformity Assessment and on amendments to certain laws, as amended;
   - **Gov. Regulation no. 582/2008 Coll.** laying down details on European technical requirements and conformity assessment procedures for medical devices (MD) under the **Medical Device Directive no. 93/42/EEC, Annex II and Directive no. 2011/65/EU**;
4. **The Manufacturing Plant** is the holder of the **Certificate of Quality Management System** according **ISO 9001:2008** (valid by Sep. 15, 2018), **Certificate of Medical Devices-Quality Management Systems** according **EN ISO 13485:2012** (valid by March 1, 2019) and **EC Certificate of the Quality Assurance System**, No. 2017-MDD/QS-015, according Annex II, excluding (4) of the Directive no. 93/42/EEC as amended by Directive 2007/47/EC, all issued by **3EC International a. s.,** Bratislava, Slovakia, Notified Body No. 2265.
5. **The above products are freely distributed and sold on the market in the Slovak Republic and the Markets of the European Economic Area, generally.**

Bratislava, 26 -05- 2017

(Place and date)

SLOVENSKÁ OBCHODNÁ A PRIEMYSELNÁ KOMORA -10- SLOVAK CHAMBER OF COMMERCE AND INDUSTRY

Certif. Seal

Juraj Knopp

(Name, signature of competent officer of SCCI)

Annex:

LIST OF MEDICAL DEVICES

of **Chirana Progress, s.r.o.(Ltd.), Piešťany**, Slovákia

Item:	*List of medical devices (MDs) (product name and Model)*	*MD Reg. no.*	*MD Class*
1.0	**HYDROTHERAPY EQUIPMENT:**		
1.1.1	LAGUNA, LAGUNA PLUS, LAGUNA BUBBLE, LAGUNA PLUS BUBBLE	P 22650	Class IIa, /Certificate valid until 16.4.2018/
1.1.2	LAGUNA TORNADO	P 22654	
1.2.1	OCEAN ECONOMY, OCEAN STANDARD, OCEAN FORTE	P 22654	
1.2.2	OCEAN DE LUXE	P 22653	
1.3.1	CASCADE, CASCADE PLUS, CASCADE DE LUXE	P 22653	
1.3.2	CASCADE SENIOR	P 26217	
1.4.1	LASTURA	P 26218	
1.4.2	LASTURA PROFI	P 26217	
1.4.3	LASTURA HOBBY	P 22562	
1.5.1	CORAL, CORAL ECONOMY	P 22562	
1.5.2	CORAL LYMFO	P 26215	
1.6.1	HUBBARDOV KÚPEĽ/ HUBBARD BATH; HUBBARDOV KÚPEĽ PLUS/ HUBBARD BATH PLUS	P 26215	
1.7.1	VOD 56, VOD 56 HT	P 26216	
1.8.1	NIAGARA, NIAGARA PLUS	P 28886	
1.9.1	ELECTRA, ELECTRA CG	P 10403	
	XXXXXXXX		

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Continue

Annex:

Item:	List of medical devices (MDs) (Product name and Model)	MD Reg. no.	MD Class
2.0	**Thermotherapy Equipment:**		
2.1	TEP	P 28471	Class I.
3.0	**CHAIRS:**		
3.1	M1, M2., M3	P 22565	Class I.
4.0	**Massage tables:**		
4.1	VOD 47	P 28483	Class I.
4.2	RELAX	P 54624	Class I.
5.0	**Accessories:**		
5.1	BUBBLE GRID	P 28482	Class I.
5.2	CIRCULAR SHOWER	P 22566	Class I.
5.3	SITZ SHOWER	P 22567	Class I.
	xxxxxxxxxx		

Ba/26.05.2017/ Ing. J. Knopp, CSc./ÚMS SOPK