Jaromír Širina **Marcela Širinová**

RQL s.r.o. U Jelena 7/109 736 01 Havířov - Šumbark

www.RQL.cz OR KOS v Ostravě oddíl C vložka 22696 **RQL@RQL.cz**

IČO 25860020 IČZ 87 442 000 DIČ CZ25860020

GLN 8594208900009 UDI-DI: 859420890GOLEMME

tel. 596 884 575 mobil: 603 822 964, 604 232 797

EU DECLARATION OF CONFORMITY

According to Regulation (EU) 2017/745/EU of the European Parliament and of the Council 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 and Act No 89/2021 Coll. on medical devices, as amended

CE

RQL s.r.o.
U Jelena 7/109, 736 01 Havířov – Šumbark
IČ 25860020, DIČ CZ25860020

It is hereby declared under the sole responsibility of the manufacturer that the medical device

Examining, treatment and operating tables and chairs GOLEM

UDI-DI: 859420890GOLEMME

Name	Code Nr.	Name	Code Nr.	Name	Code Nr.
GOLEM 6P	G 06 01	GOLEM VOJTA	G 19 01	GOLEM 3	G 50 03
GOLEM 6	G 06 02	GOLEM 1P	G 01 01	GOLEM 3T	G 50 13
GOLEM 6E	G 06 03	GOLEM 2P	G 01 02	GOLEM 3TB	G 50 23
GOLEM 6ET	G 06 04	GOLEM 3P	G 01 03	GOLEM 4	G 50 04
GOLEM 6	G 06 05	GOLEM 2S	G 04 01	GOLEM 4T	G 50 14
GOLEM 6E	G 06 06	GOLEM 4S	G 04 03	GOLEM 4TB	G 50 24
GOLEM 6ET	G 06 07	GOLEM V	G 16 01	GOLEM 4T pro ENT	G 50 34
GOLEM 6 ESP	G 06 20	GOLEM VP	G 16 02	GOLEM 5	G 50 05
GOLEM 6E ESP	G 06 21	GOLEM SKIA E	G 40 02	GOLEM 5T	G 50 15
GOLEM 6ET ESP	G 06 22	GOLEM TRANS P	G 11 02	GOLEM 5TB	G 50 25
GOLEM 6 ESP	G 06 23	GOLEM TRANS H	G 11 01	GOLEM K	G 07 01
GOLEM 6E ESP	G 06 24	GOLEM EME	G 11 03	GOLEM KP	G 07 02
GOLEM 6ET ESP	G 06 25	GOLEM TP	G 15 01	GOLEM KE	G 07 03
GOLEM 6ET	G 06 40	GOLEM T	G 15 02	GOLEM DIA P	G 09 01
GOLEM porodní	G 06 60	GOLEM PROKTOLOG	G 17 01	GOLEM DIA	G 09 02
GOLEM F1	G 00 01	GOLEM URODYNAMIC	G 18 01	GOLEM DIA E	G 09 03
GOLEM UP	G 06 50	GOLEM O	G 10 01	GOLEM 1 EXCLUSIV	G 02 01
GOLEM U	G 06 51	GOLEM RTG	G 12 01	GOLEM 2 EXCLUSIV	G 02 02
GOLEM UE	G 06 52	GOLEM SKIA P	G 40 01	GOLEM 3 EXCLUSIV	G 03 01
GOLEM ORL P	G 05 02	GOLEM 1	G 50 01	GOLEM 3E EXCLUSIV	G 03 02
GOLEM ORL E	G 05 03	GOLEM 1T	G 50 11	GOLEM 3ET EXCLUSIV	G 03 03
GOLEM ORL EE	G 05 04	GOLEM 1TB	G 50 21	ARIS 2	Z 70 01
GOLEM OD P	G 08 01	GOLEM 2	G 50 02	ARIS 3	Z 70 03
GOLEM OD	G 08 02	GOLEM 2T	G 50 12		
GOLEM OD E	G 08 03	GOLEM 2TB	G 50 22		

which is a Class I non-sterile, non-measuring medical device intended for repeated use, that the medical device is safe for its intended use under normal conditions in accordance with the enclosed instructions. The medical device also complies with the requirements of Government Regulations 118/2016, 117/2016, and 176/2008 (conformity assessment by internal device production control (Module A). The medical device complies with the conditions of European Community regulations 2017/745/EU, 2007/47/EC,2006/42/EC, 2006/95/EC, 2004/108/EC.

We have carried out an assessment of the conformity of the characteristics with the product safety requirements set out in the legal requirements and technical regulations and declare that the characteristics of the above medical device meet the requirements set out in Regulation (EU) 2017/745/EU of the European Parliament and of the Council on medical devices and that we have taken measures to ensure that the medical device complies with the requirements set out in the above legal requirements and technical regulations.

In addition, EN ISO 14971, EN 60601 (1, 1-2, 1-6, 2-46), Government Regulations 117/2016 and 118/2016 and 176/2008, EN 12182, ISO 15523-1 and Annex I MDR, EN 1041+A1 and Annex I MDR were used in the conformity assessment.

The procedure in Annex IX of Regulation (EU) 2017/745/EU of the European Parliament and of the Council on medical devices was used to assess the essential characteristics of the product in the specified manner, together with an assessment of the medical suitability of the medical device for its intended use. The technical documentation is kept by the company's managing director, Mr. Jaromir Širina. The product meets the conditions set out in Act No. 268/2014 Coll., on medical devices.

In Havirov 11.11.2021

Jaromír Širina

RQL www.RQL.cz
RQL s.r.o. U Jelena 109/7 736 01 Havířov
IČO: 25860020 DIČ: CZ25860020
603 822 964 604 232 797 596 884 575