

Jaromír Šiřina



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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 375/2022 Coll. on the implementation of certain provisions of the Act on Medical Devices and Diagnostic Medical Devices, as amended



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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 ISO 14971:2020, EN ISO 15223-1:2022 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. Jaromír Šiřina. The product meets the conditions set out in Act No. 268/2014 Coll., on medical devices Act 375/2022 Coll. on the implementation of certain provisions of the Act on Medical Devices and Diagnostic Medical Devices.

In Havířov 15.12.2022

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