Slovak Chamber of Commerce and Industry

MANUFACTURING & FREE SALE CERTIFICATE No. 004 / 2023

TO WHOM IT MAY CONCERN
UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

UNDERSIGNED AUTHORITY,

SLOVENSKÁ OBCHODNÁ A PRIEMYSELNÁ KOMORA

(SLOVAK CHAMBER OF COMMERCE AND INDUSTRY, SCCI),

Grösslingová 4, 816 03 Bratislava, Slovak Republic(SK)

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

HEREBY CERTIFIES THAT:

1. A company **BIOGEMA, výrobné družstvo, Košice,** /further only **MANUFACTURER/,** headquartered on Garbiarska 2, **Košice**, Postal code 040 01, **Slovak Republic, ID no. 00 593 222, is a Joint Stock Company** established under the laws of the Slovak Republic on 21.Dec.1988 and registered in the Commercial Register of the District Court **Košice I, Section: Dr, Insert No: 1023/V,** with the subject matter**: production and distribution of chemical, biochemical and radiochemical diagnostic kits for medical purposes; chemical and biochemical products for healthcare and cosmetic purposes;**
2. **MANUFACTURER** has its Manufacturing Plant in Košice, Slovak Republic (SK) which has been granted **permit (license) no. 2017/00187-03/PPL-Pe** for manufacturing of chemical and biochemical in vitro diagnostic medical devices under special regulations: Act no. 355/2007 Coll. as amended, by the Regional Public Health Authority in Košice on 10. Feb. 2017 (a state authority for protection, support and development of public health in the Slovak Republic).
3. **MANUFACTURER** is holder of the **Certificate No. CQS 2040/2020 of Quality Management System**, according **ISO_9001:2016** (valid up to 10. May 2023) and **Certificate No. CQS 53/2020 of Quality Management System** applicable to **Development, Production and Sale of chemical and biochemical in vitro diagnostic medical devices for healthcare purposes**, according **ISO 13485:2017** (valid up to 10, May 2023), both issued by **CQS z. s., Praha**, CZ (***CB No.3029*** *accredited by Český institut pro akreditaci, o.p.s. / Czech Accreditation Institute, Prague, CZ).*
4. **The IVDs** listed in **Annex of the M&FSC**, are registered in accordance with the **Act no. 362/2011 Coll**. with the **State Institute for Drug Control** (SIDC) in Bratislava, SK (State Supervision Authority for MDs in the Slovak Republic, EU). **The IVDs 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.:**
5. **Act no. 355/2007 Coll.** on Protection, Support and Development of Public Health and on Amendments and Supplements to Certain Acts, as amended;
6. **Act no. 362/2011 Coll.** on medicines and medical devices and on amendments to certain laws, as amended;
7. **Act no. 56/2018 Coll.** on product conformity assessment, making a determined product on the market and on the amendment of certain laws**,**
8. **DECISION no. 768/2008/EC** on a common framework for the marketing of products, and repealing **Council Decision 93/465/EEC;**
9. **REGULATION (EU) 2017/746 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU**
10. **MANUFACTURER prepared all required technical documentation, issued EC Declarations of Conformity** (EC DoC) **and affixed the CE mark on the *in vitro diagnostic MDs*, and therefore the IVDs may be freely sold in all member states of the European Union, including the Slovak Republic. Export of the IVDs outside EU is not prohibited.**
11. **This Certificate is issued to the MANUFACTURER on its request.**

BRATISLAVA, 25 -01- 2023

(Place and date)

SLOVENSKÁ OBCHODNÁ A PRIEMYSELNÁ KOMORA SLOVAK CHAMBER OF COMMERCE AND INDUSTRY -01-

Certif. Seal

Juraj Knopp

(Name, signature of competent officer of SCCI)

Form FSC_ SCCI/SOPK/ Ba V./2022/ SK

Annex to Certificate of M&FS:

LIST (1) OF MEDICAL DEVICES

BIOGEMA, v. d., Košice, SK *(Manufacturer)*

Item	*List of in vitro diagnostics (IVD) / Model , Type, ™ (MDs)*		*IVD Class*	*SIDC MDs Reg. No.*	*EC DoC / datum of issue:*
1	**IVD Test "Biogema - Elisa"** (quantitative determination of antibodies)	E-211 ELISA-anti-DNP G	Other	P 72086	EU DoC on 08 June 2021 by Manufacturer
2		E-411 ELISA-anti-DNP II G			
6		E-233 ELISA-anti-GLIADIN-native II A			
7		E-234 ELISA-anti-GLIADIN-native II G			
8		E-235 ELISA-anti-GLIADIN-native II A,G			
9		E-244 ELISA-anti-MILK II A			
10		E-245 ELISA-anti-MILK II G			
11		E-246 ELISA-anti-MILK II A,G			
12		E-244/200 ELISA-anti-MILK II A/200			
13		E-245/200 ELISA-anti-MILK II G/200			
14		E-348 ELISA-anti-ASCA II A,G			
15		E-346 ELISA-anti-ASCA II A			
16		E-347 ELISA-anti-ASCA II G			
	Kit Biogema – ELISA -anti-Gliadin " (quantitative determination of specific antibodies of class IgA and IgG against deaminated gliadin peptide)	E-230 ELISA-anti-GLIADIN-deamidated II A,G	Other	P 72086	EU DoC on 08 June 2021 by Manufacturer
		E-231 ELISA-anti-GLIADIN-deamidated II A			
		E-232 ELISA-anti-GLIADIN-deamidated II G			
17	**IVD test "Biogema-anti-CANDIDA"** (quantitative determination of igA, IgG, IgM class antibodies against Candida albicans)	E-351 ELISA anti-CANDIDA II A	Other	P 72086	EU DoC on 08 June 2021 by Manufacturer
18		E-352 ELISA-anti-CANDIDA II G			
19		E-353 ELISA-anti-CANDIDA II M			
20		E-354 ELISA-anti-CANDIDA III A,G,M			

LIST (2) OF MEDICAL DEVICES

BIOGEMA, v. d., Košice, SK *(Manufacturer)*

Item:	List of in vitro diagnostics (IVD) / Model , Type, ™ (MDs)		IVD Class	SIDC MDs Reg. No.	EC DoC / datum of issue:
21	Kit "Biogema - ELISA" (semi-quantitative determination of specific antibodies of class igA and IgG against food allergens)	E-250 ELISA-anti-CASEIN A	Other	P 72090	EU DoC on 08 June 2021 by Manufacturer
22		E-251 ELISA-anti-CASEIN G			
23		E-450 ELISA-anti-CASEINII A			
24		E-451 ELISA-anti-CASEIN II G			
25		E-260 ELISA-anti-β-LAKTOGLOBULIN A			
26		E-261 ELISA-anti-β-LAKTOGLOBULIN G			
27		E-460 ELISA-anti-β-LAKTOGLOBULIN II A			
28		E-461 ELISA-anti-β-LAKTOGLOBULIN II G			
29		E-270 ELISA-anti-LACTOSE A			
30		E-271 ELISA-anti-LACTOSE G			
31		E-470 ELISA-anti-LACTOSE II A			
32		E-471 ELISA-anti-LACTOSE II G			
33		E-280 ELISA-anti-α-LAKTALBUMIN A			
34		E-281 ELISA-anti-α-LAKTALBUMIN G			
35		E-480 ELISA-anti-α-LAKTALBUMIN II A			
36		E-481 ELISA-anti-α-LAKTALBUMIN II G			
37		E-380 ELISA-anti-OVALBUMIN A			
38		E-381 ELISA-anti-OVALBUMIN G			
39		E-440 ELISA-anti-OVALBUMIN II A			
40		E-441 ELISA-anti-OVALBUMIN II G			
41		E-390 ELISA-anti-SOYBEAN A			
42		E-391 ELISA-anti-SOYBEAN G			
43		E-490 ELISA-anti-SOYBEAN II A			
44		E-491 ELISA-anti-SOYBEAN II G			

Notice:

State Institute for Drug Control (SIDC), Medical Devices Section is CA for medical devices in the Slovak Republic. The main task of the Section is to ensure registration / notification of medical devices (MDs), to deal with incidents within the medical device vigilance system and to perform proactive and reactive market surveillance.

Ba_20-01-2023/ Ing. J. Knopp, CSc./ ÚMSaEI SOPK