Republic of Bulgaria
Executive Agency
Bulgarian Accreditation Service

Signatory to the EA Multilateral Agreement in this fied

BAS QF 2.11

ORDER

№ A 250

Sofia, 06.04.2022

Pursuant to Art 10, para. 1, item 4 and Art. 28, para. 1 of the Law on National Accreditation of Conformity Assessment Bodies and item 4.3.7. of the BAS QR 2 Accreditation Procedure in connection with an open procedure reg. № 188/181 ОКА/ПА/09.09.2021, assessment report reg. № 188/181 ОКА/ПА/8/В/15.12.2021, and statement of the Accreditation Commission reg. № 188/181 ОКА/РА/16/В/24.03.2022, I hereby

RE-ACCREDIT

INSPECTION BODY of type A

at SOFIA REGIONAL HEALTH INSPECTORATE, Sofia

Management address: 1233 Sofia, 20, Vranya Street

Office address: 1303 Sofia, 169 A, Tzar Simeon Street

To perform inspection of:

Scope type: *flexible*					
№	**Field of Inspection**	**Type of Inspection**	**Parameter of inspection/ Characteristic**	**Test and Measurement Methods Used During Inspection**	**Regulations, Standards, Specifications, Schemes**
1	**2**	**3**	**4**	**5**	**6**
1.	**PHYSICAL FACTORS**				
1.1	Artificial lighting in the work environmentresidential and public buildings	New sites and/or sites in use /operation	Illumination	Methodical instructions for measurement and assessment of artificial lighting in buildings, Standardization Publishing House, 1985 ОКА 7.1 ПК8-2	Ordinance No. 49 (SG, issue 7/1976) Ordinance No. 24 (SG, issue 95/2003) Instruction No. 34 (SG, issue 82/1975) Ordinance No. 9

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					(SG, issue 46/1994) Ordinance No. 2 (SG, issue 15/2007) Ordinance No. 3 (SG, issue 15/2007) Ordinance No. 26 (SG, issue 103/2008) БДС EN 12464-1 TS
1.2	Microclimatic parameters in the work environmentresidential and public buildings	New sites and/or sites in use /operation	- air temperature - relative humidity in air - air velocity - heat flux density	БДС 16686 Ordinance No. RD-07-3 (SG issue 63/2014) ОКА 7.1 ПК8-1	Ordinance No. 9 (SG, issue 46/1994) Ordinance No. 2 (SG, issue 15/2007) Ordinance No. 24 (SG, issue 95/2003) Ordinance No. 3 (SG, issue 15/2007) Ordinance No. 26 (SG, issue 103/2008) Instruction No. 34 (SG, issue 82/1975) Ordinance No. RD-07-3 (SG, issue 63/2014) БДС 14776 TS
1.3	Noise levels in the work environment	New sites and/or sites in use/ operation	- Daily noise exposure level - Average weekly noise exposure level - Peak sound pressure level - - Noise level - Equivalent noise level	БДС EN ISO 9612 /БДС ISO 1999/ БДС 15471 ОКА 7.1 ПК8-3/2	Ordinance No. 6 (SG, issue 70/2005) Ordinance No. 24 (SG, issue 95/2003) Ordinance No. 7 (SG, issue 88/1999) Ordinance No. 9 (SG, issue 46/1994) Ordinance No. 26 (SG, issue 103/2008) TS
1.4	Noise levels in residential and public buildings	New sites and/or sites in use /operation	- Noise level - Equivalent noise level	БДС 15471 ОКА 7.1 ПК8-3/1	Ordinance No. 6, Annex 2, Table 1 (SG, issue 58/2006) Ordinance No. 24 (SG, issue 95/2003) Ordinance No. 9 (SG, issue 46/1994)

					Ordinance No. 2 (SG, issue 15/2007) Ordinance No. 26 (SG, issue 103/2008) TS
1.5	3.3. Noise levels in residential areas	New sites and/or sites in use/ operation	Equivalent noise level	БДС 15471 ОКА 7.1 ПК8-3/1	Ordinance No. 6, Annex 2, Table 2 (SG, issue 58/2006) Ordinance No. 54, (SG, issue 3/2011) TS
1.6	4.2 Vibrations transmitted in residential premises	New sites and/or sites in use /operation	Vibration speed; Vibration acceleration	Ordinance No. 9 (SG, issue 17/ 2010) ОКА 7.1 ПК8-4	Ordinance No. 9 (SG, issue 17/2010) TS
2.	**COSMETIC PRODUCTS**				
	Cosmetic Products	New sites and/or sites in use /operation	Total number of microorganisms	NCHEM /2004 БДС EN ISO 21148 БДС EN ISO 18415 БДС EN ISO 16212 БДС EN ISO 21149 ОКА 7.1 ПК 6-2	БДС EN ISO 17516 NCHEM /2004 TS
			Staphylococcus aureus	NCHEM /2004 БДС EN ISO 21148 БДС EN ISO 18415 БДС EN ISO 22718 ОКА 7.1 ПК 6-2	
			Pseudomonas aeruginosa	NCHEM /2004 БДС EN ISO 21148 БДС EN ISO 18415 БДС EN ISO 22717 ОКА 7.1 ПК 6-2	
			Escherichia coli	NCHEM /2004 БДС EN ISO 21148 БДС EN ISO 18415 БДС EN ISO 21150 ОКА 7.1 ПК 6-2	
			Candida albicans	NCHEM /2004 БДС EN ISO 21148 БДС EN ISO 18415 БДС EN ISO 18416 ОКА 7.1 ПК 6-2	
			Heavy metals (cadmium, lead)	Collection of methods of hygiene research NCHEM – vol. IV/2002 ОКА 7.1 ПК 6-1	Regulation (EC) No. 1223/2009 TS
			pH	БДС 3741 ОКА 7.1 ПК 6-1	TS
			Thioglycolic acid (Mercaptoacetic acid)	Ordinance No. 14, Annex 2, section XVIII (SG, issue 68/2014)	

				ОКА 7.1 ПК 6-1	
			Hydrogen peroxide	Ordinance No. 14, Annex 2, section VIIIB (SG, issue 68/2014) ОКА 7.1 ПК 6-1	
			Determination of ammonia	Ordinance No. 14, Annex 2, section XVI (SG, issue 68/2014) ОКА 7.1 ПК 6-1	
			Zinc oxide Titanium dioxide	Methodology Development for inspection of the contents of UV filters and UV protection of cosmetic products, NCPHP/2007 ОКА7.1ПК6-1	
3. RAW MATERIALS FOR COSMETIC PRODUCTS					
	Raw materials for cosmetic products (Extracts to be used in cosmetic products)	New sites and/or sites in use /operation	Total number of microorganisms	NCHEM /2004 БДС EN ISO 21148 БДС EN ISO 18415 БДС EN ISO 16212 БДС EN ISO 21149 ОКА 7.1 ПК 6-2	БДС EN ISO 17516 NCHMEN/2004 TS
			Staphylococcus aureus	NCHEM /2004 БДС EN ISO 21148 БДС EN ISO 18415 БДС EN ISO 22718 ОКА 7.1 ПК 6-2	БДС EN ISO 17516 NCHMEN/2004 TS
			Pseudomonas aeruginosa	NCHEM /2004 БДС EN ISO 21148 БДС EN ISO 18415 БДС EN ISO 22717 ОКА 7.1 ПК 6-2	
			Escherichia coli	NCHEM /2004 БДС EN ISO 21148 БДС EN ISO 18415 БДС EN ISO 21150 ОКА 7.1 ПК 6-2	
			Candida albicans	NCHEM /2004 БДС EN ISO 21148 БДС EN ISO 18415 БДС EN ISO 18416 ОКА 7.1 ПК 6-2	
4. SANITARY-MICROBIOLOGICAL CONTROL OF MANUFACTURING ENVIRONMENT AND PERSONNEL					
	Sanitary-microbiological control of manufacturing environment and personnel (extracts))	New sites and/or sites in use/operation	Total number of mesophilic aerobic and facultative anaerobic microorganisms	Methodical Instruction of the Ministry of Health No. 7/1988 ОКА 7.1 ПК 7	Ordinance No. 14 (SG, issue 106/15.12.2021)
			Coliforms		
			Escherichia coli		
			Pathogens		

			Other microorganisms (molds, yeasts, etc.)		
			Listeria monocytogenes	Methodical Instruction of the Ministry of Health No. 7/1988 БДС EN ISO 11290-1 ОКА 7.1 ПК 7	

***Flexible scope:** Implementing a new version of standards/documents or standards/documents replacing them is allowed. An updated list of standards/documents and their dated versions is provided by CAB.*

Regulation (EU) No1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of November 30, 2009 cosmetic products;
Ordinance No7 on minimum requirements for health and safety at work at workplaces and during use of working equipment (SG, issue 88/1999);
Ordinance No49 on artificial lightning in buildings (SG, issue 7/1979);
Ordinance No24 on sanitary requirements to discotheques (SG, issue 95/2003);
Instruction 34 for the hygiene of sports facilities and equipment (SG, issue 82/1975);
Ordinance No9 on health and sanitary requirements during use of personal computers in training and extra-curricular activities of pupils (SG, issue 46/1994);
Ordinance No2 on health requirements to computers and internet rooms for public use (SG, issue 15/2007);
Ordinance No3 on health requirements to kindergartens (SG, issue 15/2007);
Ordinance No26 on structure and activities of crèche and baby food kitchens and health requirements to them (SG, issue 103/2008);
Ordinance NoРД-07-3 on minimum requirements for the microclimate in the work environment (SG, issue 63/2014);
Ordinance No6 on minimum requirements for securement of health and safety of workers in risks, related to noise exposure (SG, issue 70/2005);
Ordinance No6 on indicators of noise in the environment, which take into account the degree of discomfort during different parts of the day, the limit values of indicators of noise in the environment, in the premises of residential and public buildings, in areas and territories intended for housing construction, recreational areas и mixed-use areas and zones, methods for estimating the values of noise indicators and the harmful effects of noise on the health of the population (SG, issue 58/2006);
Ordinance No54 on the functions of the national environmental noise monitoring system and the requirements for conducting own monitoring and providing information from industrial noise sources in the environment (SG, issue 3/2011);
Ordinance No9 on the maximum permissible vibration values in living quarters (SG, issue 17/2010);
Compendium of methods of hygienic checks - National Centre of Hygiene, Medical Ecology and Nutrition, item IV/2002;
Methodical guidelines for measurement and evaluation of artificial lighting in buildings 40 - 85, "Standardization" Publishing house,1985 г.;
NCPHP 2007 – Methodology Development for inspection of the contents of UV filters and UV protection of cosmetic products, 2007 г., National Center for Public Health Protection;
MG of the MH No7 - Methodical guidelines of the Ministry of Health, 1988;
Ordinance No14 on determining of detailed rules for the presentation of information under Article 19, paragraph 4 of Regulation (EU) No1223/2009, with regard to cosmetic products, performance requirements for sunscreen cosmetics effectiveness and chemical methods for checking the composition of cosmetic products (SG, issue 68/2014);
Ordinance No14 on the hygiene of foodstuffs (SG, issue 106/15.12.2021);

Guidelines "Indicators and acceptable risk levels for microbiological of chemical purity of cosmetic products и methods for verifying compliance with these indicators" National Centre of Hygiene, Medical Ecology and Nutrition/2004;
TS – Technical Specification.

I ORDER

To issue the certificate of accreditation reg. № 181 OKA/06.04.2022 valid until 06.04.2026, and this order enclosed as an integral part of it.

The Certificate of accreditation with the enclosure should be obtained from the manager/ representative of the Sofia Regional Health Inspectorate, Sofia the head of the CAB, or other authorized person in the office of EA BAS.
Upon receipt of the certificate issued and enclosure, the accredited CAB is obliged to return to EA BAS the originals of the certificate of accreditation reg. № 181 OKA/30.03.2021 and its enclosure - EA BAS order reg. № A 192/30.03.2021.

This order shall be notified to the Sofia Regional Health Inspectorate, Sofia within 3 (three) days from its issuance.

Eng. Irena Borislavova

Executive Director of EA BAS