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COMPLIANCE STATEMENT

PrJSC Bio med sklo declares that the packaging glass they produce and commercialize complies with:

1. Chemical composition and resistance to chemical attack

PrJSC Bio med sklo produces a soda-lime medical glass whose main raw materials are sand, soda, limestone, dolomite, feldspar with the following composition according table:

SiO ₂	Al ₂ O ₃	Fe ₂ O ₃	CaO	MgO	Na ₂ O	K ₂ O
72±0,5	2±0,2	max 0,20	10±0,3		15±0,25	K ₂ O ≤ 1%

The glass presents a chemical agents attack resistance that meets the specification of glass type III from the GOST 19809 «Medical glass. Determination of water resistance» assuring that it is inert towards several types of attack. This characteristic allows the use of this glass as a packaging material in contact with food.

2. Applicable legislation- Glass package residues:

- TU U 23.1-04763746-027:2018 'Glass jars for food products'
- TU U 23.1-04763746-026:2018 'Glass bottles for nutrition drinks'
- DSTU 10117.1-10117.2 'Glass bottles for nutrition drinks'
- SanPiN 42-123-4240-86 'Migration limits (DKM) for chemical substances released from polymeric and other materials in contact with food products'
- NRSU-97 'Norms of Radiation Safety of Ukraine'
- Directive 94/62/EC (concerning the level of concentration of heavy metals in glass).

PrJSC Bio med sklo states that:

- no heavy metals are intentionally introduced in the glass composition
- the glass produced is analyzed to assure legal compliance.

3. Dangerous substances

The glass produced by PrJSC Bio med sklo does not include any of the dangerous substances referred to on the «Candidate list» issued by ECHA, of Arsenic, Bisphenol A, Phtalates, Benzofenone, 4 Methyl-benzofenon, Isopropyl Thioxanhone, or any other substance that may put in risk its adequacy to food contact.

4. Heavy metal migration

Regulation concerning materials and articles intended to come into contact with food foresees the adoption of specific legislation to glass. In the absence of this legislation PrJSC Bio med sklo carries out on a regular basis, heavy metals migration analyses in accordance to the international available standards and Ukrainian standards.

5. Allergens and GMO

There is no introduction of allergens or genetically modified organism in the glass produced by PrJSC Bio med sklo.

6. Reusability

Food beverage bottles and food jars can be reused.

7. Certification

PrJSC Bio med sklo is certified by ISO 13485 «Medical device» and ISO 17025 «General requirements for the competence of testing and calibration laboratories».

PrJSC Bio med sklo have FSSC 22000 and ISO 9001:2015 implementation on-going now.

Ukraine, May 23, 2019

Oksana Chegeyda, Quality Manager PrJSC Bio med sklo

