



**INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a. s.**

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**TESTING LABORATORY - TESTING DIVISION**

issues

**ATTEST**

**No. 472115959-01**

On sample:

**LUKASTERIK - Paper and Paper Bags**

Client:

**Balsac papermill s.r.o.**

**Lukavice 21, 789 01 Zábřeh, Czech Republic**

**ID: 01610368**

**Evaluation of the measured parameters:**

The evaluated samples meet in the tested parameters (see page 2) the requirements of the following standards:

- **ČSN EN 868-3** Packaging for terminally sterilized medical devices - Part 3: Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) - Requirements and test methods
- **ČSN EN 868-4** Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods

The content of the extractable epichlorohydrin from the LUKASTERIK paper bags (back sutures) in the aqueous extract prepared at the conditions 100 °C (reflux)/ 1 h is below 3 µg per kg of the back sutures.

This Attest was issued on the basis of the test report Ref. No. 472115959-01 issued on February 16, 2023.

**Issued on:** February 16, 2023

**Valid till:** February 28, 2026



**Dipl. Ing. Jiří Samsoněk, Ph.D.**  
Head of the testing laboratory

*Conditions for use of the Attest and associated information:*

1. *The Attest applies only to the sample tested by our laboratory.*
2. *The Attest remains in effect until production technology, initial materials and standards or corresponding regulations are changed; however, its validity will extend beyond the period of its effect.*
3. *If further requirements of national or EU legal regulations apply to the product, the Attest does not replace procedures and documents necessary for assessment of compliance with these regulations.*



**ATTEST**  
**No. 472115959-01**  
Values obtained:

**LUKASTERIK paper LST/60**

**Test results according to the requirements of ČSN EN 868-3**

Parameter	Unit	Value obtained	Uncertainty <sup>2)</sup>	Limit - ČSN EN 868-3
pH	-	6.5	0.5	5-8
Chlorides <sup>3)</sup>	% w/w	0.0089	0.0010	max. 0.05
Sulphates <sup>4)</sup>	% w/w	0.0026	0.0003	max. 0.25
Water resistance - from the smooth side to the rough side	s	45	4	min. 20
Water resistance - from the rough side to the smooth side	s	40	3	min. 20
Mean value of pores diameter <sup>5)</sup>	µm	12.5	0.9	max. 35

**LUKASTERIK paper bags**

**Test results according to the requirements of ČSN EN 868-4**

Parameter	Unit	Value obtained <sup>1)</sup>	Uncertainty <sup>2)</sup>	Limit - ČSN EN 868-4
pH	-	4.6	0.3	4.5-8
Chlorides <sup>3)</sup>	% w/w	0.015	0.002	max. 0.05
Sulphates <sup>4)</sup>	% w/w	0.025	0.003	max. 0.25
Epichlorhydrine	µg/l of extract	< 0.1	-	-
Epichlorhydrine	µg/kg	< 3	-	-

**Notes to the tables:**

- 1) Symbol „<” means less than limit of detection of the analytical method.
- 2) The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor of k=2, providing a level of confidence of approximately 95%.
- 3) Expressed as sodium chloride
- 4) Expressed as sodium sulphate
- 5) The equivalent pore radius was determined by bubble pressure in mm head of water on paper surface. Calculation is according to the standard.



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