

	<b>CERTIFICATE OF ANALYSIS</b> <b>DATE 18/10/2023</b>	TC-IOP-CRS-032_MOD-01 Valido dal 31/08/2023
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<b>Production Plant</b>	BEMA LANŠKROUN s.r.o.
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<b>Plant Address</b>	Dukelských hrdinů 1192, 563 01 Lanškroun
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<b>Item</b>	AF1285BM01 - MISURINO PP NEUTRO X CP28 2-15ML+CE Dis.A3363
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<b>Batch number</b>	R23020_17333788
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**1. Incoming Inspections of resing and raw materials**

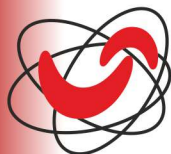
For the list of raw materials used please refer to the Declaration of Conformity attached

<b>Incoming Inspections result</b>	PASSED
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**2. Production Start-up Validation**

Control type	Nominal value	Unit	LSL	USL	Avg.	Result
Visual Check					0	passed
Weight	3,00	g	2,80	3,20	3,02	passed
Maximum Diameter Avg	37,35	mm	37,05	37,65	37,35	passed
Diam. Attachment Ribs Avg	34,90	mm	34,70	35,10	34,92	passed
Total Height	29,20	mm	28,90	29,70	29,35	passed
Verif. 2ml Notch Height	4,40	mm	4,10	4,70	0	passed
Verif. 2,5ml Notch Height	4,90	mm	4,60	5,20	0	passed
Verif. 3ml Notch Height	5,50	mm	5,20	5,80	0	passed
Verif. 4ml Notch Height	6,50	mm	6,20	6,80	0	passed
Verif. 5ml Notch Height	7,60	mm	7,30	7,90	0	passed
Verif. 6ml Notch Height	8,70	mm	8,40	9,00	0	passed
Verif. 7ml Notch Height	9,80	mm	9,50	10,10	0	passed
Verif. 7,5ml Notch Height	10,30	mm	10,00	10,60	0	passed
Verif. 8ml Notch Height	10,80	mm	10,50	11,10	0	passed
Verif. 9ml Notch Height	11,90	mm	11,60	12,20	0	passed
Verif. 10ml Notch Height	13,00	mm	12,70	13,30	0	passed
Verif. 11ml Notch Height	14,10	mm	13,80	14,40	0	passed
Verif. 12ml Notch Height	15,20	mm	14,90	15,50	0	passed
Verif. 12,5ml Notch Height	15,70	mm	15,40	16,00	0	passed
Verif. 15ml Notch Height	18,30	mm	18,00	18,60	0	passed
Verif. of Capacity	2,00	ml	1,80	2,20	2,03	passed
Check CE Mark					0	passed

<b>Start Up Validation Result:</b>	PASSED
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**BEMA**  
LANŠKROUN S.R.O.

	<b>CERTIFICATE OF ANALYSIS</b> <b>DATE 18/10/2023</b>	TC-IOP-CRS-032_MOD-01 Valido dal 31/08/2023
<b>Production Plant</b>	BEMA LANŠKROUN s.r.o.	
<b>Plant Address</b>	Dukelských hrdinů 1192, 563 01 Lanškroun	
<b>Item</b>	AF1285BM01 - MISURINO PP NEUTRO X CP28 2-15ML+CE Dis.A3363	
<b>Batch number</b>	R23020_17333788	

<b>3. In process Control:</b>	
<b>Type of control:</b>	Result
Visual/functional Inspection	passed
<b>In Process Control Result:</b>	PASSED

<b>4. Statistical Final Control:</b>	
<b>Type of control:</b>	Result
Visual/functional Inspection performed on statistical sampling	passed
<b>Statistical Final Control:</b>	PASSED
<b>Batch Notes:</b>	

**Batch Status: PASSED**

BEMA Lanškroun has implemented the Quality System Management in compliance with ISO 9001 an ISO 15378 requirements.  
The control method and quality level of the supply, except from different specification agreed with the Customer, are those defined in our internal specification.  
The batch is in compliance with the specifications and suitable for use.

Radek Dostál  
Quality manager

**BEMA Lanškroun s.r.o.**  
Dukelských hrdinů 1192, 563 01 Lanškroun  
tel.: 734 600 351  
IČ: 25999401, DIČ: CZ25999401  
email: info@bema-la.cz -3-