



BEMA
LANŠKROUN S.R.O.

SOCIETÀ / COMPANY / SOCIETE: BEMA LANŠKROUN s.r.o.
DATA / DATE / DATUM: 22/12/23

DICHIARAZIONE DI CONFORMITÀ	DECLARATION OF CONFORMITY	DECLARATION DE CONFORMITE
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ARTICOLO / ARTICLE	CS4001CX03		
DESCRIZIONE / DESCRIPTION	CAPSULA C.P.28 BIANCA INC.II-2YGR/PE2		
LOTTO / BATCH / LOT	R23021_73536072		
PRODUCTION DATE	18/12/23	PRODUCTION END DATE:	22/12/23
PLANT ADDRESS	Dukelských hrdinů 1192, 563 01 Lanškroun		

Si dichiara che la merce riferita al lotto sopraindicato, ricevuta con fornitura indicata nel DDT sopraspacificato, allegato al presente documento, è stato controllato ed è risultato essere Conforme alle specifiche del prodotto. Il metodo di controllo ed il livello qualitativo della fornitura, salvo diversi capitoli specificatamente approvati, sono quelli definiti nelle nostre specifiche interne.

Nous déclarons que la marchandise en référence au lot ci-dessous indiqué, recue avec la facture en référence à le BL Indiquée ci-dessus, en pièce joint au document, il a été contrôlé et déclaré CONFORME aux spécifications du produit. La méthode de contrôle et le niveau de qualité de la fourniture, exception faite pour les cahiers des charges approuvés Se réfère à nos spécifications internes.

We declare that the goods referred to the lot indicated above, received with the supply indicated in the aforementioned delivery note and attached to this document, have been tested and resulted to be IN ACCORDANCE with the product technical specifications.

The control method and quality level of the supply, unless different specifications agreed with the Customer, are those defined in our Quality System.

The materials used to manufacture the supplied item comply with the following provisions:

- Regulations applicable to articles intended for contact with food:
 - Reg. 10/2011 UE and following amendments
 - Reg. 1895/2005/CE; Reg. 1935/2004/CE; Reg. 2023/2006/CE
 - DPR 777/82 and following amendments; D.M. 21/03/1973 and following amendments; D.Lgs 25/01/1992 n. 108;
 - D.Lgs 10/02/2017, n. 29

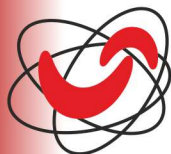
to receive the Declaration of Conformity in compliance with the above-mentioned regulations and Ministerial Decrees, please refer

to your sales contact in BEMA Lanškroun s.r.o.

- Dir 94/62/EEC: relative to the content of heavy metals
- Class I Medical Devices with measuring function, with CE0373 marking, are in compliance with Dir 93/42/EEC - Annex I please refer to attached DoC signed by Legal Representative
- Dir 75/324/EEC and subsequent updates (Dir 2008/47/EC): applicable to aerosol generators

COMPONENT	COMPONENT DESCRIPTION
L1 CS1055ZZZ	SOTTOCAPSULA PER C.P. PFP 28 PP NEUTRO
L1 CS1057B17A	COPRICAPSULA C.P.28 PP BIANCA INC.1-2-Dis.A5379
L1 CS1360ZZZ	ANELLO TE PER CPTE 28 LDPE NEUTRO Dis.A5226

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L1 YGR/PE2	LINER POLESPAN PE2 D.25,40 mm SP.1,20 mm (Y027) LP
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MATERIAL	COMPONENT		MATERIAL DESCRIPTION
TPPC/PUR315M-A	CS1055ZZZ	PP	PP COPO PURELL RP315M PHARMA GRADO 8 c/processing aid
WSAN/MB2	CS1055ZZZ	PP	SCIV.CESA SLIP MB2 (SANDOLUBE)
TPPC/PUR315M-A	CS1057B17A	PP	PP COPO PURELL RP315M PHARMA GRADO 8 c/processing aid
WBIA/601	CS1057B17A	PP	MASTER BIANCO CPF 601 (M) B17
WSAN/MB2	CS1057B17A	PP	SCIV.CESA SLIP MB2 (SANDOLUBE)
TLDPE1922	CS1360ZZZ	PE	SABIC LDPE PCG22 (SABIC 1922T)
WSAN/MB2	CS1360ZZZ	PE	SCIV.CESA SLIP MB2 (SANDOLUBE)

Radek Dostál
Quality manager

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