

DICHIARAZIONE DI CONFORMITÀ / DECLARATION OF CONFORMITY

BEMA Lanškroun is currently certified according to EU directive 93/42/CEE for the production of Medical Devices of class I with measuring function and the related certificate has been released in 2019 with expiry date 26, May 2024.

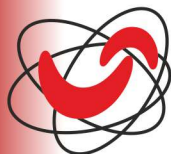
Article 120 of MDR defines that "The certificates issued by notified bodies in accordance with directives 90/385 and 93/42/EEC starting from May 2017 remain valid until the end of period indicated in the certificate [...] They shall however become void at the latest on 27 May 2024"

Certificate No.: QPM-0036-19, **date of issue:** 24/06/2019, **expiry date:** 26/05/2024

Issued by: Istituto Superiore Sanità, Notified Body number 0373.

The below listed medical product(s) complies with the Medical Devices Directive No. 93/42/EEC and subsequent amendments.

PRODUCT NAME	ITEM CODE	ITEM DESCRIPTION
Dosage cups (engraved) not sterile	From AF 0081 to AF 1999	Accessory for pharmaceutical dosage (using engraved level notches) Ø24mm and Ø28mm from 1.5ml to 50ml - class Im
Dosage cups (decorated), not sterile	From AF 5101 to AF 5999	Accessory for pharmaceutical dosage (using decorated level notches) Ø24mm and Ø28mm from 1.5ml to 50ml - class Im
Dosage cups and spoons (engraved), not sterile	From AF 2104 to AF 2999	Accessory for pharmaceutical dosage (using engraved level notches) Ø24mm and Ø28mm from 1.5ml to 50ml - class Im
Dosage syringes (engraved), not sterile	From AF 4019 to AF 4999	Accessory for pharmaceutical dosage (using engraved level notches) from 7ml to 20ml - class Im
Dosage syringes (decorated), not sterile	From AF 6128 to AF 6999	Accessory for pharmaceutical dosage (using decorated level notches) from 0.2ml to 10ml - class Im
Dropper with Tamper Evident cap, not sterile	From AF 711 to AF 736	Assembled accessory for pharmaceutical dosage From Ø18mm to Ø28mm from 0.25ml to 2ml - class Im



PRODUCT NAME	ITEM CODE	ITEM DESCRIPTION
Dropper with Child Proof cap, not sterile	From CS 711 to CS 736	Assembled accessory with child-proof feature for pharmaceutical dosage From Ø18mm to Ø28mm from 0.25ml to 2ml - class Im

- **Composition of article code**

Medical Devices, as well as other BEMA Lanškroun products, are described by an article code composed as follows:

FIRST SEGMENT		SECOND SEGMENT	
AA	NNNN	BB	NN
category of article	Mold or technological process	Specific characteristics	Progressive number

The first segment of the code (AA + NNNN) is instead descriptive of the category of article (measuring spoon, dosing syringe...) and of the type of technology used to obtain the finished article (injection, assembly, decoration...).

The second segment, on the other hand, concerns customizations or specific characteristics (for example in terms of type of packaging, custom decoration for the customer...).

All the Medical Devices covered by this Declaration are fulfill all essential requirements (Annex I – MDD 93/42/EEC) and therefore the **CE - CONFORMITY MARK** is applied.

Radek Dostál
Quality manager

BEMA Lanškroun s.r.o.
Dukelských hrdinů 1192, 583 01 Lanškroun
tel.: 734 600 351
IČ: 25999401, DIČ: CZ25999401
email: info@bema-la.cz -3-