bormioli pharma
A Gerresheimer Company

QS/26/062/ML
To: Whom It May Concern

SUBJECT: BORMIOLI PHARMA MDD CERTIFICATE "QPM-0036-19" EXTENSION

Medical devices items: dosage spoon, dosage cup, dosage syringe for oral liquid administration.
Medical device classification: class I with measuring function.
Manufacturing sites: Rivanazzano (IT), Castelguelfo (IT), Saint Sulpice (FR).

Dear Customer,

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

We, as the manufacturer declare under our sole responsibility:

- the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the medical devices we manufacture are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- certificate No.: **QPM-0036-19**, covering the devices, was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards. Bormioli Pharma 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.
- devices continue to comply with Directive 93/42/EEC, with no significant changes in the design and intended purpose, and they do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.
- no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9).
- formal application to the Notified Body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made and a signed written agreement **ref. number AOO-ISS-23/05/2024-0022616**, is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.

Considered that article 120 of MDR has been amended extending the validity of the certificate to December 31, 2028, for device in class I with measurement function, Bormioli Pharma is allowed to market MDs in accordance with regulatory requirements and under the active certificate until the 31/12/2028.

Here following the details on EU directive 93/42/CEE certificate:

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

Extension as per (EU) 2023/607 Regulation until: **31/12/2028**

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

Indeed, it must be pointed out that Bormioli Pharma will commit to gain certification to EU Regulation 2017/45 within the due date 31/12/2028.

Parma, 04th May 2026

Erika Minari
Quality Manager Plastic