Sol M Building a Healthier Tomorrow

Warsaw, 26th of June, 2023

Re: To Whom it may concern

To purpose of this letter is to provide the clarification for not providing the Instructions for Use (IFUs) for selected products.

The intended use and operation mode of the listed devices is well known for the end users and customers.

They are used by the trained healthcare professionals in performing clinical procedures such as filling a syringe and injecting its content to the patient.

All necessary information for a safe use is provided as the standardized symbols on the blister/ box/ case. Whenever necessary, indication about the activation safety feature or way of using the product is described using icons printed on the shelf box.

On the base of the European Union Regulation No. 2017/745 on the Medical Devices (MDR), Annex I, art 23.1 d) says "*…By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions…"* no additional Instruction for Use is provided with the devices.

Sincerely,

Giulio Falconi

Giulio Falconi
Senior Director,
EMEA Marketing

EUROPE OFFICE
SOL-MILLENNIUM Europe Sp. z o.o.
The HUB, Rondo Daszyńskiego 2B,
00-847 Warsaw,
Poland

+ 48 22 202 67 23
info.eu@solm.com
www.sol-m.com

The Registry Court: The District Court for the Capital City of Warsaw, XIIth Commercial Division of the National Court Register
KRS 0000434783, EU VAT:PL5252535720, Share capital: 500.000 PLN