

<b>Manufacturer and Plant</b>	Alle S.r.l. Via Chizzalunga 1, 36066 Sandrigo (VI) Italy Tel.: + 39 0444 656111 - Fax.: + 39 0444 656199
<b>Medical Device Type</b>	INVASIVE, DISPOSABLE, STERILE
<b>Product Category(ies)</b>	Infusion sets for pump and accessories (connectors, extension lines)
<b>Classification</b>	Class IIa according to rule n. 5 of the Annex IX MDD 93/42EC and its updates
<b>Procedure to the CE Certificate</b>	According to Annex V of the Directive 93/42EC and its updates
<b>CE CERTIFICATE</b>	G2 098477 0002 Rev.1 date: 2020/02/17 valid until: 2024/05/26
<b>Start EC mark date</b>	<b>2020/02/17</b>
<b>Notified Body ID n.</b>	<b>0123</b> ; TUV SUD Product Service GmbH Zertifierstelle-Ridlerstrasse 65, 80339 Munchen - Germany

The manufacturer **Alle S.r.l.** declares, under its own responsibility, that the product listed below meets the requirements of the Directive 93/42/EEC, incorporated in Italy with Italian legislative decree 46 of February 24, 1997 and subsequent updates and amended by the directive 2007/47/EC and also declares that the same device has been manufactured according to the applicable harmonized standard EN ISO 13485:2016.

Code	Description
270601	IRRIGATION SET FOR MACHINERY
270602	IRRIGATION SET FOR MACHINERY
270603	IRRIGATION SET FOR MACHINERY
270604	IRRIGATION SET FOR MACHINERY
270606	IRRIGATION SET FOR MACHINERY
270607	IRRIGATION SET FOR MACHINERY
270609	IRRIGATION SET FOR MACHINERY
270610	IRRIGATION SET FOR MACHINERY
270613	IRRIGATION SET FOR MACHINERY
270616	IRRIGATION SET FOR MACHINERY
270617	IRRIGATION SET FOR MACHINERY
270618	IRRIGATION SET FOR MACHINERY
270619	IRRIGATION SET FOR MACHINERY
270621	IRRIGATION SET FOR MACHINERY
270622	IRRIGATION SET FOR MACHINERY
270623	IRRIGATION SET FOR MACHINERY
270624	IRRIGATION SET FOR MACHINERY
270625	IRRIGATION SET FOR MACHINERY
270626	TUBING EXTENSION FOR MECHANICAL IRRIGATION
270901	IRRIGATION SET FOR MACHINERY
270902	IRRIGATION SET FOR MACHINERY
270630	MANUAL IRRIGATION SET
270634	IRRIGATION SET FOR MACHINERY
270635	IRRIGATION SET FOR MACHINERY
270636	IRRIGATION SET FOR MACHINERY
270637	IRRIGATION SET FOR MACHINERY
270638	IRRIGATION SET FOR MACHINERY
270639	IRRIGATION SET FOR MACHINERY
270640	IRRIGATION SET FOR MACHINERY
MED-0300	IRRIGATION SET FOR MACHINERY
MED-0301	IRRIGATION SET FOR MACHINERY

## APPLICABLE STANDARDS

General Standards and Technical Standards are listed in Annex n.8 Technical File FT01

## VALIDITY

This declaration of conformity is valid until 2024/05/26.

Sandrigo, **15/01/2023**

CEO

Nicola Basso

