 <b>Elcam MEDICAL</b> <small>Where everything connects</small>	<b>Declaration Of Conformity (DoC)</b>	February 11, 2024
	<b>PureSite Closed Male Connector + Accessories</b>	out of 1Page 2

**Manufacturer:**                      Name:    Elcam Medical ACAL

Address:   Baram 1386000, Israel

Single Registration Number: IL-MF-000012189

**Device Name:**                      PureSite Closed Male Connector + Accessories

**Device Item Number:**    270724, 270725

**Devices Covered:**                      All PureSite Closed Male Connector (CMC) manufactured from the date this declaration is signed and as long as this revision of the declaration is in effect

**Intended Purpose of the Product**                      The PureSite Closed Male Connector (CMC) is a bi-directional flow, needle-free luer access device used as an accessory to an IV administration set and/or syringe. It is intended for preparation and administration of parenteral fluids, including hazardous drugs.

   The PureSite Dust Cover Cap is an accessory to the PureSite Closed Male Connector to prevent touch contamination during transport

**Classification:**                      Class 1s per Rule 2 of Annex VIII of the EU Medical Devices Regulation 2017/745

**Conformity Assessment Route:**                      Annex IX - Chapter I of the EU Medical Devices Regulation 2017/745

**EU QMS certificate number:**                      D2001100013

**European Authorised Representative:**                      Name:    MedNet EC-REP GmbH

Address:   Borkstraße 10, 48163 Münster, Germany

DE-AR-000000002


**Notified Body:**                      mdc (NB Number 0483)

**Notified Body Address:**                      Kriegerstr. 6, 70191 Stuttgart, Germany

**Basic UDI-DI:**                      UDI-DI #729010259EM00001RY

**Swiss CH – REP**                      Name:    MedNet SWISS GmbH

Address:   D4 Platz 4, 6039 Root D4, Switzerland

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We hereby declare that the medical device specified above meets the provisions of Regulation (EU) MDR 2017/745 concerning medical devices. This declaration is supported by the Quality Management System certification under BS EN ISO 13485:2021 issued by mdc.

We further declare that Elcam Medical ACAL is exclusively responsible for this Declaration of Conformity.

Yaniv Menachem;  
Regulatory Affairs Manager

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Name and Title

**Elcam Medical**

**A.C.A.L**

\_\_\_\_\_  
Signature

Baram, Israel;

*February 11, 2024*

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Place and Date