


EU Declaration of Conformity

According to the **REGULATION (EU) 2017/745 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL**
Class I Medical Device (non-sterile)

On the basis of the referenced test report(s), sample(s) tested of the below product have been found to comply with the standards harmonized with the directives listed on this verification at the time the tests were carried out. Other standards and Directives may be relevant to the product. This verification is part of the full test report(s) and should be read in conjunction with it <them>.

Applicant Name:	Edma Group, LLC
Address:	3634 E Piccadilly Rd, Phoenix, AZ 85018,USA
Product Description:	Edma Synthetic Nitrile Examination Gloves
Models/Type References:	EDM-002
Standard(s)/Directive(s):	EN ISO 13485:2016 EN ISO 14971:2012 EN 1041:2008 EN ISO 15223-1:2016 EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN 62366-1:2015 EN455-1:2000 EN455-2:2015 EN455-3:2015 EN455-1:2020
Conformity assessment procedure:	EU Declaration of Conformity + Technical Documentation (Annex II) + Technical Documentation on Post-Market Surveillance (Annex III)
EC representative:	Share Info GmbH
Address:	Heerdter Lohweg 83, 40549 Düsseldorf
Singed on: 23 Apr.	Place: 3634 E Piccadilly Rd, Phoenix, AZ 85018,USA
Authorized by:	



Signature 
General manager: Viorel Nicolae Cretu
Place: 3634 E Piccadilly Rd, Phoenix, AZ 85018
Date: Apr. 23, 2021

