

CONFORMITY DECLARATION

MANUFACTURER	SANTEX S.p.A.
<i>Head office</i>	Via S. Giovanni sul Muro, 1 - 20121 Milano (MI) - ITALY
<i>Medical Device & Commercial offices</i>	Via Massina, 10 – 36040 Sarego (VI)
<i>Healthcare offices</i>	Via Alberto Santurro, 2 – 36040 Meledo (VI)
PRODUCTS	EGOSAN® All-in-Ones Natural Comfort Vita Soft EGOSAN® Pants Natural Comfort EGOSAN® Anatomic Shaped pad Natural Comfort EGOSAN® Belted all-in-one diapers Natural Comfort EGOSAN® Light Men Bladder control pads for Men EGOSAN® Light Bladder control pads EGOSAN® Rectangular pads
CLASSIFICATION	I non sterile without measuring function
REFERENCE VALUATION QUALITY	Annex XI of MDR 2017/745
<p>WE DECLARE THAT THE PRODUCT AFOREMENTIONED IS IN CONFORMITY WITH THE PRESCRIPTIONS OF THE REGULATION (EU) 2017/745.</p> <p>The present statement was issued in compliance with the Annex XI of MDR 2017/745 under the supervision of Manufacturer.</p> <p>All the technical documentation is kept by the QCM in the QMS archives at the Meledo (VI) offices - Via A. Santurro, 2 - 36040 for a period of not less than 10 years.</p>	
STANDARDS APPLIED	MDR 2017/745 UNI EN ISO 9001:2015 UNI EN ISO 13485:2016 UNI CEI EN ISO 14971:2020
NOTIFY BODY	N.A. (SELF CERTIFICATION)
NUMBER OF CERTIFICATION	N.A. (SELF CERTIFICATION)
VALIDITY OF CONFORMITY DECLARATION	From 05/05/2021
PLACE AND DATE OF CURRENT ISSUE	Sarego, 26/07/2021
SIGNATURE	Quality Manager: Dr. Alessandro Zogno <i>SANTEX S.p.A.</i> <i>Rappresentante della Direzione</i> <i>Per la Qualità</i> <i>(Dr. Alessandro Zogno)</i>