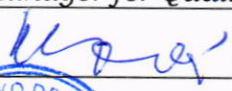




saniteks

DECLARATION OF CONFORMITY

Name and address of the producer	SANITEKS d.d., ul Tone Hrovata br. 2, 77230 Velika Kladuša, Bosna i Hercegovina
Name of Product/ medical device	Plaster of Paris bandages
Design of product	Width 5 – 30 cm, Lenght 2 – 5 m
Class of Product	I, rule 1
Category of Product	X- disposable product
Essential requirements	According to Annex I, Directive for Medical Devices 93/42/EEC
Applied directive and Annex for conformity assessment	Directive for Medical devices 93/42/EEC, Annex VII and Appendix to Directive 2007/47/EC
Applied standards and regulations	Standards harmonized with Directives 93/42/EEC and 2007/47/EC, laws, rule books and quidelines for Medical devices
Notification body	Det Norske Veritas Certification AS, Veritasveien 1, 1322 Hovik, Norway, Identification No. 0434
ISO Certificate 13485:2012, No.	168983-2014-AQ-HRV-NA
Number	01-190/17
EC Representative	Dr. Dario Giovanardi, Via castelletto, n. 63 36016 Thiene (VI), Italia E-mail: dario.giovanardi@poste.it dario.giovanardi@libero.it
Date	04.05.2017. years
Person in charge	Ahmet Žalić, Executive Manager for Quality and Development
Signature of Person in charge	
Stamp	