

EC Declaration of Conformity

Manufacturers Name:	Whitney Products Inc. dba Whitney Medical Solutions	
Manufacturers Address:	5737 W. Howard St. Niles, IL 60714 USA	
Authorized Representative Name:	QualRep Services B.V.	
Authorized Representative Address:	Utrechtseweg 310 - Bldg B42 NL-6812 AR Arnhem The Netherlands	
Name of the Device (s):	eShield Sterile	
Product codes:	EC2100	eShield Sterile™ Cell Phone Size
	EC2200	eShield Sterile™ Digital Camera Size with adhesive ring in the package
	EC2300	eShield Sterile™ Tablet Size
	EC2400	eShield Sterile™ SLR Camera Size with sterile rubber band
Classification:	Is (Class I sterile)	
Notified Body name:	GMED SAS	
Notified Body Address:	Head Office: 1, Rue de Gaston Boissier 75015 Paris France	
Notified Body Identification number:	0459	
Conformity assessment route:	WHITNEY MEDICAL SOLUTIONS uses the following procedures for the CE-labeling of their products according to the Regulation MDD 93/42/EC: Class Is: EC conformity declaration according to annex V, section 3.	
<p>This declaration of conformity is issued under the sole responsibility of WHITNEY MEDICAL SOLUTIONS. We hereby declare that the medical device(s) specified above meet the provision of the Directive (EU) MDD 93/42/EC, revision M5, dated 21.9.2007 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by GMED SAS.</p> <p>All supporting documentation is retained at the premises of the manufacturer.</p>		
Signature:  STEVEN G. WHITNEY PRESIDENT		Place and date of issue: September 16, 2021 Niles, IL 60714 



Attachment to declaration of conformity eShield Sterile Covers

eShield Sterile Covers

Device commercial reference code	Device designation
EC2100	eShield Sterile™ Cell Phone Size
EC2200	eShield Sterile™ Digital Camera Size
EC2300	eShield Sterile™ Tablet Size
EC2400	eShield Sterile™ SLR Camera Size