

DECLARATION OF CONFORMITY

Legal Manufacturer:	WELLEX Company Limited Cairo-Ismailia desert Road, Ismailia Public Free Zone, 41639 Ismailia City, Egypt
Manufacturing Site(s):	WELLEX Company Limited Cairo-Ismailia desert Road, Ismailia Public Free Zone, 41639 Ismailia City, Egypt
EU Authorized Representative:	MDSS GmbH Schiffgraben 41, 30175 Hannover, Germany
Product:	Ureteral Stents and Sets Intended Use: are used to ensure the patency of a ureter, which may be compromised, for example, by a kidney stone. Used for temporary internal drainage from the renal pelvis to the bladder , to prevent damage to a blocked kidney, until a procedure to remove the stone can be performed. A listing of Codes is included in Attachment 1 of this document.
Classification:	Class IIa device in conformity with Annex IX, Rule 5 in the Medical Device Directive 93/42/EEC (amended by 2007/47/EC)
Standards Applied conform complying of the product with the regulatory requirements	<ul style="list-style-type: none">• ASTM F1828-17 (2017)• EN ISO 11070:2014 + A1: 2018• EN ISO 13485:2016 + /AC:2018• EN ISO 15223-1:2016• EN ISO 14644-1:2015• EN ISO 11135:2014• EN ISO 11607-1:2017

- EN ISO 11607-2:2017
- EN ISO 14971:2012
- EN ISO 10993-1:2009 + /AC:2010
- EN ISO 10993-3:2014
- EN ISO 10993-5:2009
- EN ISO 10993-6:2016
- EN ISO 10993-7:2008 + /AC:2009
- EN ISO 10993-10:2013
- EN ISO 10993-11:2018

We, WELLEX Company limited, declare that the products identified above are in conformity with all relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices (amended by 2007/47/EC). This declaration is made under Annex V of this directive. All Supporting Information is retained under the control of WELLEX Company limited.

Notified Body

G.F.I. Health Technology Certification Ltd
Jacovides Tower 81-83 Grivas Digenis Avenue -
1090 Nicosia, Cyprus

EC Notified Body Number**2803**

EC Certificates	
Certificate Name	Certificate Number / Validity
Annex V, Certificate number	
EN ISO 13485:2016 Certificate Number	

Date of First CE Marking: DD MM YY**Signature, Date of Issue:****Name:** Angie Ahmed**Title:** Director, Regulatory Affairs**Signature:** Angie Ahmed **Date:** 02 Jan. 2020**Name:** Ahmed Mohammady**Title:** CEO of WELLEX Company**Signature:** Ahmed Mohammady **Date:** 02 Jan. 2020