

Manufacturer's Declaration of Conformity
(in accordance with ISO/IEC 1750-1)

No: 050-271-100929-7
Issuer's Name: Cook Incorporated
Issuer's Address: 750 Daniels Way
Bloomington, IN, 47404
USA

Object of the Declaration: Technical File 050-271 Transjugular Sets
HTPS, LABS, TJC, RABS, RTPS, RUPS, NST, RMT, RM
(A complete listing of part numbers is attached)

Classification: I

Conformity Assessment Route: Annex I

The above Object of the Declaration fulfills the requirements of council **Directive 93/42/EEC** of 14 June 1993, as amended by Council **Directive 2007/47/EC** of 5 September 2007, and is in conformity with the requirements of the following standards:

Standard	Title	Date of Issue
ISO 13485:2003	Urinary bags	2003
ISO 9001:1996	Dilation catheters	2009
ISO 9001:1996	Accessories	2009
ISO 13485:2003	Catheter syringes	2008
ISO 9001:1996	Ureteral catheters/ Occlusion catheters	2007
ISO 9001:1996	Stone baskets	2008
ISO 13485:2003	Ureteral access sheath.	2003
ISO 13485:2003	Urinalysis set	2006

Notified Body: Lloyd's Register Quality Assurance
Middlemarch Office Village, Sisken Drive
Coventry CV3 4FJ; United Kingdom

European Representative: William Cook Europe
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Bjæverskov, Denmark

Signed For and On Behalf of: Cook Incorporated

Signature: 

Name: Lisa Webb, MBA, RAC
Position: Regulatory Affairs Manager
Location: Bloomington, IN; USA
Date: 29 September 2010

Supplier's Declaration of Conformity (in accordance with ISO/IEC 17050-1)
No. 050-271-100929-7