

# EC DECLARATION OF CONFORMITY FOR INTERMITTENT URETHRAL CATHETER

This is a declaration made in accordance with the requirements of the relevant provisions of Annex I of the Medical Devices Directive 93/42/EEC as amended by 2007/47/EC and the UK Medical Devices Regulations 2002, SI 2002/618 as amended by SI 2008 / 2936 and have been subject to the conformity assessment procedures laid out in Annex V.

**Legal Name:** IVOR SHAW LIMITED t/a PENNINE HEATHCARE

**Business Address:** 300 City Gate  
London Road  
Derby  
DE24 8BY

**EU Authorised Representative:** Advena Ltd. Tower Business Centre,  
2<sup>nd</sup> Floor, Tower Street, Swatar, BKR 4013, Malta

**Medical Devices:** Intermittent Urethral Catheter

**Classification:** I (Sterile) Rule 5

**GMDN:** Intermittent Nelaton Catheter, Intermittent Female Catheter, Prelubricated Intermittent Nelaton Catheter, Prelubricated Female Catheter - 64266

**Intended use:** Intermittent urethral catheters are used to facilitate intermittent bladder drainage.

**Category:** MD 0100 General non-active, non-implantable medical devices

**Under the supervision of the Notified Body:** BSI Group The Netherlands B.V

**With the Notified Body Number:** 2797

**Notified Body Certificate Number:** CE 648427

**Conformity of assessment:** EC Declaration of Conformity in accordance with Annex VII of the Medical Device Directive coupled with Production Quality Assurance outlined in Annex V.

Signed By:

*M. Arun*

Name: **Arun Mahendran**

Date:

18 November 2020

Position: **Head of Regulatory Affairs**

On behalf of IVOR SHAW LTD t/a Pennine Healthcare

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

**Product List:**

<b>Product Code</b>	<b>Product Description</b>
FC-1406	Catheter, Intermittent, Female 23cm 6ch PVC
FC-1406/1	Catheter, Intermittent, Female 23cm 6ch PVC
FC-1406/18/1	Catheter, Intermittent, Female 18cm 6ch PVC
FC-1408	Catheter, Intermittent, Female 23cm 8ch PVC
FC-1408/1	Catheter, Intermittent, Female 23cm 8ch PVC
FC-1408/18/1	Catheter, Intermittent, Female 18cm 8ch PVC
FC-1408/TRE	Catheter, Intermittent, Female 23cm 8ch PVC
FC-1410	Catheter, Intermittent, Female 23cm 10ch PVC
FC-1410/1	Catheter, Intermittent, Female 23cm 10ch PVC
FC-1410/18/1	Catheter, Intermittent, Female 18cm 10ch PVC
FC-1410/BULK/TP*	Catheter, Intermittent, Female 23cm 10ch PVC Bulk
FC-1410/FP	Catheter, Intermittent, Female 23cm 10ch PVC Drug Tarrif
FC-1410/TRE	Catheter, Intermittent, Female 23cm 10ch PVC
FC-1412	Catheter, Intermittent, Female 23cm 12ch PVC
FC-1412/1	Catheter, Intermittent, Female 23cm 12ch PVC
FC-1412/18/1	Catheter, Intermittent, Female 18cm 12ch PVC
FC-1412/BULK*	Catheter, Intermittent, Female 23cm 12ch PVC Bulk
FC-1412/FP	Catheter, Intermittent, Female 23cm 12ch PVC
FC-1412/TRE	Catheter, Intermittent, Female 23cm 12ch PVC
FC-1414	Catheter, Intermittent, Female 23cm 14ch PVC
FC-1414/1	Catheter, Intermittent, Female 23cm 14ch PVC
FC-1414/18/1	Catheter, Intermittent, Female 18cm 14ch PVC
FC-1414/BULK*	Catheter, Intermittent, Female 23cm 14ch PVC Bulk
FC-1414/FP	Catheter, Intermittent, Female 23cm 14ch PVC Drug Tarrif
FC-1416	Catheter, Intermittent, Female 23cm 16ch PVC

FC-1416/1	Catheter, Intermittent, Female 23cm 16ch PVC
FC-1416/18/1	Catheter, Intermittent, Female 18cm 16ch PVC
FC-1418	Catheter, Intermittent, Female 23cm 18ch PVC
FC-1418/1	Catheter, Intermittent, Female 23cm 18ch PVC
FC-1418/18/1	Catheter, Intermittent, Female 18cm 18ch PVC
FC-1606	Catheter, Intermittent Pre-lubricated female 23cm 6fg PVC
FC-1608	Catheter, Intermittent Pre-lubricated female 23cm 8fg PVC
FC-1608/FP	Catheter, Intermittent Pre-lubricated female 23cm 8fg PVC Drug Tarrif
FC-1610	Catheter, Intermittent Pre-lubricated female 23cm 10fg PVC
FC-1610/10	Catheter, Intermittent Pre-lubricated female 23cm 10fg PVC
FC-1610/FP	Catheter, Intermittent Pre-lubricated female 23cm 10fg PVC Drug Tarrif
FC-1610/IT	Catheter, Intermittent Pre-lubricated female 23cm 10fg PVC
FC-1612	Catheter, Intermittent Pre-lubricated female 23cm 12fg PVC
FC-1612/10	Catheter, Intermittent Pre-lubricated female 23cm 12fg PVC
FC-1612/FP	Catheter, Intermittent Pre-lubricated female 23cm 12fg PVC Drug Tarrif
FC-1612/IT	Catheter, Intermittent Pre-lubricated female 23cm 12fg PVC
FC-1614	Catheter, Intermittent Pre-lubricated female 23cm 14fg PVC
FC-1614/FP	Catheter, Intermittent Pre-lubricated female 23cm 14fg PVC Drug Tarrif
FC-1614/IT	Catheter, Intermittent Pre-lubricated female 23cm 14fg PVC
FC-1616	Catheter, Intermittent Pre-lubricated female 23cm 16fg PVC
FC-1616/FP	Catheter, Intermittent Pre-lubricated female 23cm 16fg PVC Drug Tarrif
NC-1206/FP/25	Catheter, Intermittent, Female 28cm 6ch PVC Drug Tarrif
NC-1206/SW	Catheter, Intermittent Standard (Nelaton) 38cm 6ch Single Wrap PVC
NC-1206/SW/1	Catheter, Intermittent Standard (Nelaton) 38cm 6ch Single Wrap PVC
NC-1208/FP/25	Catheter, Intermittent Standard (Nelaton) 25cm 8ch Single Wrap PVC Drug Tarrif
NC-1208/SW	Catheter, Intermittent Standard (Nelaton) 38cm 8ch Single Wrap PVC
NC-1208/SW/1	Catheter, Intermittent Standard (Nelaton) 38cm 8ch Single Wrap PVC
NC-1210/BULK*	Catheter, Intermittent Standard (Nelaton) 38cm 10ch PVC Bulk

NC-1210/DW	Catheter, Intermittent Standard (Nelaton) 38cm 10ch Double Wrap PVC
NC-1210/DW/TRE	Catheter, Intermittent Standard (Nelaton) 38cm 10ch Double Wrap PVC
NC-1210/FP/25	Catheter, Intermittent, Female 25cm 10ch PVC Drug Tarrif
NC-1210/SW	Catheter, Intermittent Standard (Nelaton) 38cm 10ch Single Wrap PVC
NC-1210/SW/1	Catheter, Intermittent Standard (Nelaton) 38cm 10ch Single Wrap PVC
NC-1212/BULK*	Catheter, Intermittent Standard (Nelaton) 38cm 12ch PVC Bulk
NC-1212/BULK/TP*	Catheter, Intermittent Standard (Nelaton) 38cm 12ch PVC Bulk
NC-1212/DW	Catheter, Intermittent Standard (Nelaton) 38cm 12ch Double Wrap PVC
NC-1212/DW/TRE	Catheter, Intermittent Standard (Nelaton) 38cm 12ch Double Wrap PVC
NC-1212/FP	Catheter, Intermittent Standard (Nelaton) 38cm 12ch Single Wrap PVC Drug Tarrif
NC-1212/SW	Catheter, Intermittent Standard (Nelaton) 38cm 12ch Single Wrap PVC
NC-1212/SW/1	Catheter, Intermittent Standard (Nelaton) 38cm 12ch Single Wrap PVC
NC-1214/BULK*	Catheter, Intermittent Standard (Nelaton) 38cm 14ch PVC Bulk
NC-1214/DW	Catheter, Intermittent Standard (Nelaton) 38cm 14ch Double Wrap PVC
NC-1214/DW/TRE	Catheter, Intermittent Standard (Nelaton) 38cm 14ch Double Wrap PVC
NC-1214/FP	Catheter, Intermittent Standard (Nelaton) 38cm 14ch Single Wrap PVC Drug Tarrif
NC-1214/SW	Catheter, Intermittent Standard (Nelaton) 38cm 14ch Single Wrap PVC
NC-1214/SW/1	Catheter, Intermittent Standard (Nelaton) 38cm 14ch Single Wrap PVC
NC-1216/DW	Catheter, Intermittent Standard (Nelaton) 38cm 16ch Double Wrap PVC
NC-1216/FP	Catheter, Intermittent Standard (Nelaton) 38cm 16ch Single Wrap PVC Drug Tarrif
NC-1216/SW	Catheter, Intermittent Standard (Nelaton) 38cm 16ch Single Wrap PVC
NC-1216/SW/1	Catheter, Intermittent Standard (Nelaton) 38cm 16ch Single Wrap PVC
NC-1218/BULK*	Catheter, Intermittent Standard (Nelaton) 38cm 18ch PVC Bulk
NC-1218/SW	Catheter, Intermittent Standard (Nelaton) 38cm 18ch Single Wrap PVC
NC-1218/SW/1	Catheter, Intermittent Standard (Nelaton) 38cm 18ch Single Wrap PVC
NC-1220/SW	Catheter, Intermittent Standard (Nelaton) 38cm 20ch Single Wrap PVC
NC-1220/SW/1	Catheter, Intermittent Standard (Nelaton) 38cm 20ch Single Wrap PVC
NC-1222/SW	Catheter, Intermittent Standard (Nelaton) 38cm 22ch Single Wrap PVC

NC-1222/SW/1	Catheter, Intermittent Standard (Nelaton) 38cm 22ch Single Wrap PVC
NC-1224/SW	Catheter, Intermittent Standard (Nelaton) 38cm 24ch Single Wrap PVC
NC-1608	Catheter, Intermittent Pre-lubricated Standard (Nelaton) 43cm 8g PVC
NC-1608/BG/FP	Catheter, Intermittent Pre-lubricated with Integral Bag, Standard (Nelaton) 43cm 8fg Double PVC Drug Tarrif
NC-1608/FP	Catheter, Intermittent Pre-lubricated Standard (Nelaton) 43cm 8fg PVC Drug Tarrif
NC-1610	Catheter, Intermittent Pre-lubricated Standard (Nelaton) 43cm 10fg PVC
NC-1610/BG	Catheter, Intermittent Pre-lubricated with Integral Bag, Standard (Nelaton) 43cm 10fg PVC
NC-1610/BG/FP	Catheter, Intermittent Pre-lubricated with Integral Bag, Standard (Nelaton) 43cm 10fg PVC Drug Tarrif
NC-1610/FP	Catheter, Intermittent Pre-lubricated Standard (Nelaton) 43cm 10fg PVC Drug Tarrif
NC-1610/IT	Catheter, Intermittent Pre-lubricated Standard (Nelaton) 43cm 10fg PVC
NC-1612	Catheter, Intermittent Pre-lubricated Standard (Nelaton) 43cm 12fg PVC
NC-1612/10	Catheter, Intermittent Pre-lubricated Standard (Nelaton) 43cm 12fg PVC
NC-1612/BG	Catheter, Intermittent Pre-lubricated with Integral Bag, Standard (Nelaton) 43cm 12fg PVC
NC-1612/BG/FP	Catheter, Intermittent Pre-lubricated with Integral Bag, Standard (Nelaton) 43cm 12fg PVC Drug Tarrif
NC-1612/FP	Catheter, Intermittent Pre-lubricated Standard (Nelaton) 43cm 12fg PVC Drug Tarrif
NC-1612/IT	Catheter, Intermittent Pre-lubricated Standard (Nelaton) 43cm 12fg PVC
NC-1614	Catheter, Intermittent Pre-lubricated Standard 43cm 14fg PVC
NC-1614/10	Catheter, Intermittent Pre-lubricated Standard 43cm 14fg PVC
NC-1614/BG	Catheter, Intermittent Pre-lubricated with Integral Bag, Standard (Nelaton) 43cm 14fg PVC
NC-1614/BG/FP	Catheter, Intermittent Pre-lubricated with Integral Bag, Standard (Nelaton) 43cm 14fg PVC Drug Tarrif
NC-1614/FP	Catheter, Intermittent Pre-lubricated Standard 43cm 14fg PVC Drug Tarrif
NC-1614/IT	Catheter, Intermittent Pre-lubricated Standard 43cm 14fg PVC
NC-1616	Catheter, Intermittent Pre-lubricated Standard 43cm 16fg PVC
NC-1616/BG	Catheter, Intermittent Pre-lubricated with Integral Bag, Standard 43cm 16fg PVC
NC-1616/BG/FP	Catheter, Intermittent Pre-lubricated with Integral Bag, Standard 43cm 16fg PVC Drug Tarrif

NC-1616/FP	Catheter, Intermittent Pre-lubricated Standard 43cm 16fg PVC Drug Tarrif
NC-1616/IT	Catheter, Intermittent Pre-lubricated Standard 43cm 16fg PVC
NC-1708	Catheter, Intermittent Formed End Standard (Tiemann) 38cm 8fg PVC
NC-1708/IT	Catheter, Intermittent Formed End Standard (Tiemann) 38cm 8fg PVC
NC-1710	Catheter, Intermittent Formed End Standard (Tiemann) 38cm 10fg PVC
NC-1710/IT	Catheter, Intermittent Formed End Standard (Tiemann) 38cm 10fg PVC
NC-1712	Catheter, Intermittent Formed End Standard (Tiemann) 38cm 12fg PVC
NC-1712/IT	Catheter, Intermittent Formed End Standard (Tiemann) 38cm 12fg PVC
NC-1714	Catheter, Intermittent Formed End Standard (Tiemann) 38cm 14fg PVC
NC-1714/IT	Catheter, Intermittent Formed End Standard (Tiemann) 38cm 14fg PVC
NC-1716	Catheter, Intermittent Formed End Standard (Tiemann) 38cm 16fg PVC
NC-1716/IT	Catheter, Intermittent Formed End Standard (Tiemann) 38cm 16fg PVC
NC-1718	Catheter, Intermittent Formed End Standard (Tiemann) 38cm 18fg PVC
NC-1910	Catheter, Intermittent Pre-lubricated Formed End Standard (Tiemann) 43cm 10fg PVC Drug Tarrif
NC-1912	Catheter, Intermittent Pre-lubricated Formed End Standard (Tiemann) 43cm 12fg PVC Drug Tarrif

**\* Added to procedure pack or supplied as non-sterile to Procedure Pack/Kit makers**