

## EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Yushin Medical**  
**36, Jomaru-ro 427beon-gil,**  
**Bucheon-si, Gyeonggi-do, 14558, Rep. of KOREA**

Name and address of the authorised representative **MPS Medical Products Service GmbH**  
**Bornegasse 20**  
**35619 Braunfels**  
**Germany**

We declare under our sole responsibility that

the medical device: **Foley Balloon Catheters**  
**GMDN-Code : 34917(2-way), 32331(3-way)**

### 2-way, Normal type

1001-06, 1001-08, 1001-10, 1002-12, 1002-14, 1002-16, 1002-18,  
1002-20, 1002-22, 1002-24, 1002-26, 1001-06-1, 1001-08-1, 1001-10-1,  
1002-12-1, 1002-14-1, 1002-16-1, 1002-18-1, 1002-20-1, 1002-22-1,  
1002-24-1, 1002-26-1, 1007-06OT, 1007F-06OT, 1007-06OT-1, 1007F-  
06OT-1,  
1004-14, 1004-16, 1004-18, 1004-20, 1004-22, 1004-24, 1004-26,  
1004-14-1, 1004-16-1, 1004-18-1, 1004-20-1, 1004-22-1, 1004-24-1,  
1004-26-1

### 3-way, Normal type

1005-14, 1005-16, 1005-18, 1005-20, 1005-22, 1005-24, 1005-26,  
1006-14, 1006-16, 1006-18, 1006-20, 1006-22, 1006-24, 1006-26,  
1006S-18

### 2-way, UniBal type

1001UB-08, 1001UB-10, 1002UB-12, 1002UB-14, 1002UB-16, 1002UB-  
18, 1002UB-20, 1002UB-22, 1002UB-24, 1002UB-26, 1001UB-08-1,  
1001UB-10-1, 1002UB-12-1, 1002UB-14-1, 1002UB-16-1, 1002UB-18-  
1, 1002UB-20-1, 1002UB-22-1, 1002UB-24-1, 1002UB-26-1,  
1002UBS-12, 1002UBS-14, 1002UBS-16, 1002UBS-18, 1002UBS-20,  
1002UBS-22, 1002UBS-24, 1002UBS-26, 1002UBS-12-1, 1002UBS-14-  
1, 1002UBS-16-1, 1002UBS-18-1, 1002UBS-20-1, 1002UBS-22-1,  
1002UBS-24-1, 1002UBS-26-1,  
1001UB-08B, 1001UB-10B, 1002UB-12B, 1002UB-14B, 1002UB-16B,  
1002UB-18B, 1002UB-20B, 1002UB-22B, 1002UB-24B, 1002UB-26B,  
1003UB-12B, 1003UB-14B, 1003UB-16B, 1003UB-18B, 1003UB-20B,  
1003UB-22B, 1003UB-24B, 1003UB-26B,  
1003UB-10, 1003UB-12, 1003UB-14, 1003UB-16, 1003UB-18, 1003UB-  
20, 1003UB-22, 1003UB-24, 1003UB-26, 1003UB-10-1, 1003UB-12-1,  
1003UB-14-1, 1003UB-16-1, 1003UB-18-1, 1003UB-20-1, 1003UB-22-  
1, 1003UB-24-1, 1003UB-26-1,  
1007UB-08, 1007UB-10, 1007UB-12, 1007UB-14, 1007UB-16, 1007UB-  
18, 1007UB-20, 1007UB-22, 1007UB-24, 1007UB-26, 1007UB-08-1,  
1007UB-10-1, 1007UB-12-1, 1007UB-14-1, 1007UB-16-1, 1007UB-18-  
1, 1007UB-20-1, 1007UB-22-1, 1007UB-24-1, 1007UB-26-1,  
1007UBS-08, 1007UBS-10, 1007UBS-12, 1007UBS-14, 1007UBS-16,  
1007UBS-18, 1007UBS-20, 1007UBS-22, 1007UBS-24, 1007UBS-26,  
1007UBS-08-1, 1007UBS-10-1, 1007UBS-12-1, 1007UBS-14-1,  
1007UBS-16-1, 1007UBS-18-1, 1007UBS-20-1, 1007UBS-22-1,

1007UBS-24-1, 1007UBS-26-1,  
1007UBF-08, 1007UBF-10, 1007UBF-12, 1007UBF-14, 1007UBF-16,  
1007UBF-18, 1007UBF-20, 1007UBF-22, 1007UBF-24, 1007UBF-26,  
1007UBF-08-1, 1007UBF-10-1, 1007UBF-12-1, 1007UBF-14-1,  
1007UBF-16-1, 1007UBF-18-1, 1007UBF-20-1, 1007UBF-22-1,  
1007UBF-24-1, 1007UBF-26-1,  
1007UB-08OT, 1007UB-10OT, 1007UB-12OT, 1007UB-14OT, 1007UB-  
16OT, 1007UB-18OT, 1007UB-20OT, 1007UB-22OT, 1007UB-24OT,  
1007UB-26OT, 1007UB-08OT-1, 1007UB-10OT-1, 1007UB-12OT-1,  
1007UB-14OT-1, 1007UB-16OT-1, 1007UB-18OT-1, 1007UB-20OT-1,  
1007UB-22OT-1, 1007UB-24OT-1, 1007UB-26OT-1,  
1007UBS-08OT, 1007UBS-10OT, 1007UBS-12OT, 1007UBS-14OT,  
1007UBS-16OT, 1007UBS-18OT, 1007UBS-20OT, 1007UBS-22OT,  
1007UBS-24OT, 1007UBS-26OT, 1007UBS-08OT-1, 1007UBS-10OT-  
1, 1007UBS-12OT-1, 1007UBS-14OT-1, 1007UBS-16OT-1, 1007UBS-  
18OT-1, 1007UBS-20OT-1, 1007UBS-22OT-1, 1007UBS-24OT-1,  
1007UBS-26OT-1,  
1007UBF-08OT, 1007UBF-10OT, 1007UBF-12OT, 1007UBF-14OT,  
1007UBF-16OT, 1007UBF-18OT, 1007UBF-20OT, 1007UBF-22OT,  
1007UBF-24OT, 1007UBF-26OT, 1007UBF-08OT-1, 1007UBF-10OT-1,  
1007UBF-12OT-1, 1007UBF-14OT-1, 1007UBF-16OT-1, 1007UBF-  
18OT-1, 1007UBF-20OT-1, 1007UBF-22OT-1, 1007UBF-24OT-1,  
1007UBF-26OT-1

2-way, Tiemann type

1011-10, 1011-12, 1011-14, 1011-16, 1011-18, 1011-20, 1011-22,  
1011-24, 1011-10-1, 1011-12-1, 1011-14-1, 1011-16-1, 1011-18-1,  
1011-20-1, 1011-22-1, 1011-24-1,  
1011-10B, 1011-12B, 1011-14B, 1011-16B, 1011-18B, 1011-20B, 1011-  
22B, 1011-24B,  
1011B-10, 1011B-12, 1011B-14, 1011B-16, 1011B-18, 1011B-20,  
1011B-22, 1011B-24, 1011B-10-1, 1011B-12-1, 1011B-14-1, 1011B-16-  
1, 1011B-18-1, 1011B-20-1, 1011B-22-1, 1011B-24-1,  
1014-14, 1014-16, 1014-18, 1014-20, 1014-22, 1014-24, 1014-26,  
1014-14-1, 1014-16-1, 1014-18-1, 1014-20-1, 1014-22-1, 1014-24-1,  
1014-26-1,  
1011UB-10, 1011UB-12, 1011UB-14, 1011UB-16, 1011UB-18, 1011UB-  
20, 1011UB-22, 1011UB-24, 1011UB-10-1, 1011UB-12-1, 1011UB-14-  
1, 1011UB-16-1, 1011UB-18-1, 1011UB-20-1, 1011UB-22-1, 1011UB-  
24-1

2-way, Integrated type

1001F-08, 1001F-10, 1002F-12, 1002F-14, 1002F-16, 1002F-18,  
1002F-20, 1002F-22, 1002F-24, 1002F-26, 1001F-08-1, 1001F-10-1,  
1002F-12-1, 1002F-14-1, 1002F-16-1, 1002F-18-1, 1002F-20-1, 1002F-  
22-1, 1002F-24-1, 1002F-26-1,  
1001F-08B, 1001F-10B, 1002F-12B, 1002F-14B, 1002F- 16B, 1002F-  
18B, 1002F- 20B, 1002F- 22B, 1002F- 24B, 1002F- 26B

3-way, Irrigation type

1037B-18, 1037B-20, 1037D-22, 1037D-24, 1037D-26, 1038B-18,  
1038B-20, 1038D-22, 1038D-24, 1038D-26, 1039B-18, 1039B-20,  
1039D-22, 1039D-24, 1039D-26

of class:

**IIb**

according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC as amended by 2007/24/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

## Foley Balloon Catheters

Conformity assessment procedure: **Directive 93/42/EEC Annex II**

Registration No.: **HD 60134200 0001**

Applied standards:

EN 556-1:2001/AC:2006	EN ISO 11607-1:2009/A1:2014
EN 1041:2008	EN ISO 11607-2:2006/A1:2014
EN ISO 15223-1:2016	EN ISO 11737-1:2006/AC:2009
EN ISO 10993-1:2009	EN ISO 11737-2:2009
EN ISO 10993-3:2014	ISO 14644-1:2015
EN ISO 10993-5:2009	ISO 14644-2:2015
EN ISO 10993-7:2008	EN ISO 14971:2012
EN ISO 10993-10:2013	EN 1616:1997/A1:1999
EN ISO 10993-11:2009	EN 20594-1:1993/A1:1997
EN ISO 10993-12:2012	EN 62366:2008
EN ISO 11135-1:2007	EN ISO 13485:2016
EN ISO 11138-1:2017	
EN ISO 11138-2:2017	

Notified Body:

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Bucheon, 2019.01.15.

  
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K H Lee  
Quality Management Representative