MarFlow
MEDICAL EQUIPMENT

EC DECLARATION OF CONFORMITY.

We declare under our sole responsibility that the product

Medical Device: **Biliary Stents - Standard**
REF: **BSS 7/3, BSS 7/4, BSS 7/5, BSS 7/6, BSS 7/7, BSS 7/8, BSS 7/9, BSS 7/10, BSS 7/11, BSS 7/12, BSS 7/13, BSS 7/14, BSS 7/15, BSS 8.5/3, BSS 8.5/4, BSS 8.5/5, BSS 8.5/6, BSS 8.5/7, BSS 8.5/8, BSS 8.5/9, BSS 8.5/10, BSS 8.5/11, BSS 8.5/12, BSS 8.5/13, BSS 8.5**

The product meets the provisions of the MDD 93/42/EEC with amendment directive 2007/47/EC concerning medical devices which apply to them.

The devices meet the essential requirement according Annex I of the MDD 93/42/EEC including the amendments according 2007/47/EC.

The MD is classified (Class IIb) according to annex IX of the Medical Device Directive,
We herewith declare the conformity according to Annex II.

The Notified body certified the Medical device: 3EC International a.s., Hranicna 18, 821 05 Bratislava, Slovakia, Notified Body No. 2265

Following standards were used to prove the products conformity with the essential requirements of the above Directive:

BS EN 980:2008, EN ISO 13485:2012, ISO 15223-1-2012, BS EN 1041-2008, EN ISO 14971-2012, EN 62366:2008, EN ISO 11135-1:2007, EN ISO 10993-1:2009, EN ISO 10993-3:2009, EN ISO 10993-5:2009, EN ISO 10993-6:2009.

For
Marflow AG, Adliswil / Zürich - Switzerland
Position: Managing Director
Date: 15.06.2016