

# SHEFFMED

BRITISH INNOVATION GLOBAL CONSCIENCE

---

## **Urgent Field Safety Notice**

**All products listed on attached Appendix A.  
Ref. FSN070818  
Identify and Quarantine affected batches**

---

Date: 7<sup>th</sup> August 2018

Attention: Procurement Department

### **Details on affected devices:**

Please refer to the enclosed list of affected medical devices.

### **Description of the problem:**

Following Sheffmed taking responsibility for cleanroom activities from a subcontractor, the medical devices listed have been released without the appropriate regulatory assessments and scrutiny of a notified body as required by the Medical Device Directive.

### **Advise on action to be taken by the user:**

On receipt of this notification please immediately:

- identify and quarantine any of the affected devices,
- return these affected devices to  
Device Recall, Sheffmed Ltd, 38-40 Clifton Street, SHEFFIELD, S9 2DQ, or  
request collection of products
- Respond by email or post to acknowledge receipt of this notification and with  
details regarding the status of the affected devices received

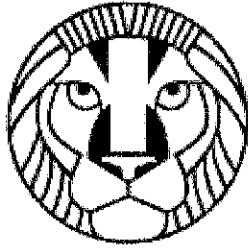
### **Transmission of this Field Safety Notice:**

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Sheffmed Ltd, 38-40 Clifton Street, Don Valley, Sheffield S9 2DQ.

Tel: +44(0)114 261 7161 Fax: +44(0)114 261 0161 Email: [sales@sheffmed.com](mailto:sales@sheffmed.com) Web: [www.sheffmed.com](http://www.sheffmed.com)

Sheffmed Limited Registered in England & Wales No. 4065406 VAT No. 763 8419 01



# SHEFFMED

BRITISH INNOVATION GLOBAL CONSCIENCE

**Contact reference person:**

Name: Sandra Brown, Quality Manager  
E-mail: [sandra@sheffmed.com](mailto:sandra@sheffmed.com)  
Tel: 0114 261 7161

The undersign confirms that this notice has been notified the appropriate Regulatory Agency

*S. Brown*  
08 AUG 18

Sandra Brown  
Quality Manager

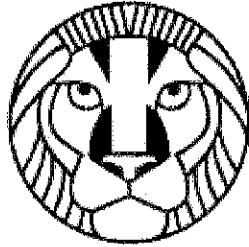
*A McNulty*  
08 AUG 18

Alan McNulty  
Director

Sheffmed Ltd, 38-40 Clifton Street, Don Valley, Sheffield S9 2DQ.

Tel: +44(0)114 261 7161 Fax: +44(0)114 261 0161 Email: [sales@sheffmed.com](mailto:sales@sheffmed.com) Web: [www.sheffmed.com](http://www.sheffmed.com)

Sheffmed Limited Registered in England & Wales No. 4065406 VAT No. 763 8419 01



# SHEFFMED

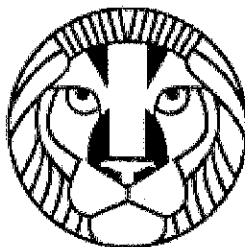
BRITISH INNOVATION GLOBAL CONSCIENCE

APPENDIX A – 07/Aug/18

Sheffmed Ltd, 38-40 Clifton Street, Don Valley, Sheffield S9 2DQ.

Tel: +44(0)114 261 7161 Fax: +44(0)114 261 0161 Email: [sales@sheffmed.com](mailto:sales@sheffmed.com) Web: [www.sheffmed.com](http://www.sheffmed.com)

Sheffmed Limited Registered in England & Wales No. 4065406 VAT No. 763 8419 01



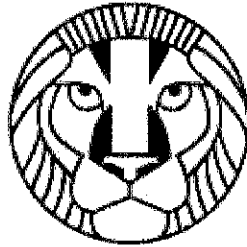
# SHEFFMED

BRITISH INNOVATION GLOBAL CONSCIENCE

Product Code	Description	Batch No.
P20-150	Disposable Suction Kit, Pack of 50	23680-170920C
		23810-171231C
S11-249S	Disposable Poole Suction Tube, Long	IS33-9-180211-1
S11-250S	Disposable Poole Suction Tube, Small	PC/18/1691
		PC/18/1707
S11-329S	Disposable Poole Suction Tube, Medium	PC/18/1704
		PC/18/1707
S11-330S	Disposable Crocodile Forceps, Micro	PC/18/1694
		PC/18/1704
		18/0309/1029
		18/0316/1032
S11-338S	Disposable Henckel Forceps	PC/18/1714
S11-345S	Disposable Micro Scissor, 5mm Jaw	PC/18/1704
SP0117S	Disposable Lemperts Section Tube, 9fg	PC/18/1719
TE10-190S	Disposable St. Barts Blunt Hook	PC/18/1700
		PC/18/1703
TE10-213S	Tilley Aural Forceps, 140mm	PC/18/1698
		18/0223/1025
		PC/18/1704
		18/0309/1029
		18/0316/1032

Tel: +44(0)114 261 7161 Fax: +44(0)114 261 0161 Email: [sales@sheffmed.com](mailto:sales@sheffmed.com) Web: [www.sheffmed.com](http://www.sheffmed.com)

Sheffmed Limited Registered in England & Wales No. 4065406 VAT No. 763 8419 01



# SHEFFMED

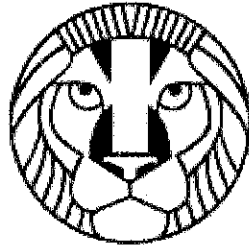
BRITISH INNOVATION GLOBAL CONSCIENCE

Product Code	Description	Batch No.
TE11-204S	Stapes Hook, Angled	PC/18/1707
		PC/18/1710
TE11-207S	Stapes Hook, Straight	PC/18/1704
		PC/18/1405
TE11-241S	Disposable Crocodile Forceps, Std	PC/18/1704
		PC/18/1714
TE11-310S	Biopsy Forceps, 2mm x 1mm Jaw, 85mm	PC/18/1700
		PC/18/1704
TE11-311S	Biopsy Forceps, 3mm x 2mm Jaw, 85mm	PC/18/1710
TE15-102S	Denis Browne Tonsil Forceps, 200mm	PC/18/1698
TE15-121S	Negus Pusher, 200mm	PC/18/1704
TE15-131NGS	St. Clair Curette, 14mm, w/o Guard	PC/18/1703
TE15-132S	St. Clair Adenoid Curette, 16mm	SA16/010731
TE15-141S	Davis Boyle Mouth Gag, Child	PC/18/1714
TE15-142S	Davis Boyle Mouth Gag, Adult	PC/18/1700
		PC/18/1714
TE15-153S	Tongue Plate, Slotted, 3.5-Inch	PC/18/1703
		PC/18/1704

Sheffmed Ltd, 38-40 Clifton Street, Don Valley, Sheffield S9 2DQ.

Tel: +44(0)114 261 7161 Fax: +44(0)114 261 0161 Email: [sales@sheffmed.com](mailto:sales@sheffmed.com) Web: [www.sheffmed.com](http://www.sheffmed.com)

Sheffmed Limited Registered in England & Wales No. 4065406 VAT No. 763 8419 01



# SHEFFMED

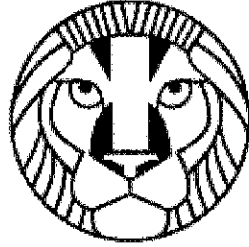
BRITISH INNOVATION GLOBAL CONSCIENCE

Product Code	Description	Batch No.
TE15-154S	Tongue Plate, Slotted, 4.0-Inch	PC/18/1698
		PC/18/1710
TE15-157S	Draffin Bipod, Pair	PC/18/1700
TE16-116S	Disposable Laryngeal Mirror, w/ Handle, 22mm	PC/16/1563
TG12-126S	Metz Scissor, Curved, 180mm	PC/18/1698
TG12-162S	Disposable Iris Scissor, Curved, 110mm	PC/18/1710
TG22-108S	Disposable Mayo Needle Holder, 180mm	PC/18/1704
TG24-135S	Disposable Jobson Horne Probe, 178mm	PC/18/1691
TG25-113S	Mollinson Pillar Retractor	PC/18/1704
		PC/18/1719
TG32-294R	Disposable Cannula Rubber Olive, Box of 10	18/0309/1029
		PC/18/1714
TG35-100S	Disposable Yankauer Suction Tube	PC/18/1714
TG35-139S	Disposable Schuknecht Suction Tube, 24swg	PC/18/1704

Sheffmed Ltd, 38-40 Clifton Street, Don Valley, Sheffield S9 2DQ.

Tel: +44(0)114 261 7161 Fax: +44(0)114 261 0161 Email: [sales@sheffmed.com](mailto:sales@sheffmed.com) Web: [www.sheffmed.com](http://www.sheffmed.com)

Sheffmed Limited Registered in England & Wales No. 4065406 VAT No. 763 8419 01



# SHEFFMED

BRITISH INNOVATION GLOBAL CONSCIENCE

Product Code	Description	Batch No.
TS11-411S	Disposable Crocodile Forceps, 80mm Shaft, 5mm F	18/0223/1025
		18/0309/1029
		18/0316/1032
		PC/18/1703
		PC/18/1704
		PC/18/1707
		PC/18/1714
		PC/18/1719

Sheffmed Ltd, 38-40 Clifton Street, Don Valley, Sheffield S9 2DQ.

Tel: +44(0)114 261 7161 Fax: +44(0)114 261 0161 Email: [sales@sheffmed.com](mailto:sales@sheffmed.com) Web: [www.sheffmed.com](http://www.sheffmed.com)

Sheffmed Limited Registered in England & Wales No. 4065406 VAT No. 763 8419 01