



By Royal Charter

# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**No.**

**CE 606566**

**Issued To:**

**Sheffmed Limited  
38-40 Clifton Street  
Sheffield  
S9 2DQ  
United Kingdom**

In respect of:

**The manufacture of sterile suction tubes.**

**Those aspects of Annex V concerned with securing and maintaining sterility in the manufacture of class I surgical instruments.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-02-12**

Date: **2020-11-18**

Expiry Date: **2024-03-02**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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## Supplementary Information to CE 606566

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Number	Device	Intended Purpose per IFU
<b>Class II a</b>		
MD 0106	Suction tube	Used as an accessory to a low power suction pump for the removal of waste body materials during and post Ear Nose & Throat (ENT) Surgery. In addition the device may be used for general suctioning of waste body materials during clinical use for the ear, nose and throat area of the body. Transient, surgically invasive
<b>Class I s</b>		
MD 0106	Ointment applicator (single use) - syringe with tip sterile	Used in the ear canal to apply ointment (not supplied with product). Not for surgically invasive use.
MD 0106	Suction controller (single use) sterile	Used to control flow of suction from the ear canal. Not for surgically invasive use
MD 0106	Forceps (single use) sterile (Henkel, Tilley)	Used in procedure for the ear canal such as removing ear wax (Henkel), and the Tilley for anterior nasal packing. Not for surgically invasive use
MD 0106	Forceps - Crocodile (single use) - sterile	Used in procedure for the ear canal such as removing ear wax or foreign objects, or placing foreign objects in the ear. Not for surgically invasive use.

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Number	Device	Intended Purpose per IFU
<b>Class I s</b>		
MD 0106	Disposable micro scissors	Used in procedures for the ear canal and nose such as cutting ear wax or foreign objects. Not for surgically invasive use.
MD 0106	ENT Probes (single use) - Jobson, St Barts, Formby sterile	Used in ear canal for removing and retracting tissue/wax. Not for surgically invasive use.
MD 0106	Uterine cannula (single use) sterile	Manipulation of uterus and manual injection of fluid to allow for contrast, prior to X-Ray imaging. Not for surgically invasive use.
MD 0106	Mouth gags	Retracting mouth. Not for surgically invasive use.
MD 0106	Tongue plates	Depressing tongue. Not for surgically invasive use.
MD 0106	Mouth gag support (single use) Draffin Bipod	Holding mouth gag does not contact patient. Not for surgically invasive use.
MD 0106	Mouth gag support (single use) Magauran plate	Holding mouth gag does not contact patient. Not for surgically invasive use.

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Number	Device	Intended Purpose per IFU
<b>Class I s</b>		
MD 0106	Tonsil forceps Denis Browne	Holding tonsils. Not for surgically invasive use.
MD 0106	Biopsy forcep, single use, sterile.	These are cup forceps, used in procedure for the ear canal and nose such as removing ear wax or foreign objects. Not for surgically invasive use.
MD 0106	House Curette	Used to in the ear to scrape ear wax. Not for surgically invasive use.
MD 0106	Mollinson Pillar retractor	Used to retract soft tissue within tonsilectomy procedure. Not for surgically invasive use.

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Number	Device	Intended Purpose per IFU
<b>Class I s</b>		
MD 0106	Gwynne Evans Dissector	Use to push tonsils to one side for tonsilectomy procedure. Not for surgically invasive use.
MD 0106	Trousseau tracheal dilator	Open up the throat Not for surgically invasive use.
MD 0106	Plastic specula	To place in the ear to allow visual examination, to protect the cavity during surgery, allowing surgical instruments to be easily inserted, used and removed without damaging the ear canal, for use in clinics not in theatres. Not for surgically invasive use.

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