

**CODMAN NEURO**



**Declaration of Conformity**

**CODMAN® Neurosurgical High Speed Drill System: ET-500 Rev. H –  
Class IIa Rule 6**

**Manufacturer:**

**Codman & Shurtleff, Inc.**  
325 Paramount Drive  
Raynham, MA 02767-0350  
USA

*Authorised representative*

**Codman**

A division of Johnson & Johnson Medical Ltd.  
Pinewood Campus,  
Nine Mile Ride,  
Wokingham, RG40 3EW  
United Kingdom

**Notified Body:**

BSi

Identification Number: 0086

**Production Assurance Certificate CE 56021**

**MDD Annex V**

**Products:**

See attached list

**Classification:** IIa, Rule 6 of Annex IX of the MDD 93/42/EEC

We declare that the above-mentioned products meet the provisions of the *legislation Directive 93/42/EEC* concerning Medical Devices into the laws of the European Economic area. All supporting documentation is available under the premises of the manufacturer.

**Start of CE Marking:** See Attached referencing date of CE 02281 issuance

Title: DECLARATION OF CONFORMITY – Appendix 2

Number: WI-190003

Revision: 6

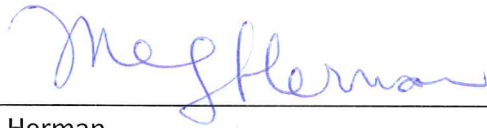
CO Number: 103018819

Type: Non PPE

Class: Work Instruction

Release Level: Production

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Megan Herman

Senior Regulatory Affairs Specialist

**ELENA JUGO**

Digitally signed by ELENA JUGO  
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Elena Jugo

Senior Regulatory Affairs Manager

23/July/2015

22/JUL/2015

SMH

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22/JUL/2015

Title: DECLARATION OF CONFORMITY – Appendix 2

Number: WI-190003

Revision: 6

CO Number: 103018819

Type: Non PPE

Class: Work Instruction

Release Level: Production

**ET-500 Rev. H**

| PRODUCT CODE | DESCRIPTION                                       | Sterile/<br>Non-Sterile | CE MARK<br>DATE | GMDN<br>CODE | GMDN CODE<br>DESCRIPTION     |
|--------------|---|-------------------------|-----------------|--------------|------------------------------|
| 93-5100      | Nosepiece, straight, 50mm                         | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5101      | Nosepiece, straight with Snap, 113mm              | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5102      | Nosepiece, angled with Snap, 132 mm               | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5110      | Nosepiece, straight, 70mm                         | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5111      | Nosepiece, straight with Snap, 113mm              | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5112      | Nosepiece, angles with Snap, 150mm                | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5120      | Nosepiece, straight, 110mm                        | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5121      | Nosepiece, straight with Snap, 175mm              | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5122      | Nosepiece, angled with Snap, 195mm                | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5181      | Craniotome;, small Cutting depth 11.5mm           | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5183      | Craniotome, medium, Cutting depth 14.5mm          | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5185      | Craniotome, large, Cutting depth 24.5mm           | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5191      | Craniotome rotating, small, Cutting depth 11.5mm  | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5193      | Craniotome rotating, medium, Cutting depth 14.5mm | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5195      | Craniotome rotating, large, Cutting depth 24.5mm  | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5303      | Fluted Ball Tip Cutter @ 2.4mm, short             | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5305      | Fluted Ball Tip Cutter @ 3.2mm, short             | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5307      | Fluted Ball Tip Cutter @ 4.8mm, short             | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5310      | Fluted Ball Tip Cutter @ 6.4mm, short             | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5312      | Fluted Ball Tip Cutter @ 7.9mm, short             | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5323      | Diamond Ball Tip @ 1.0mm, smooth, short           | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5325      | Diamond Ball Tip @ 1.5mm, smooth, short           | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |

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| PRODUCT CODE | DESCRIPTION                             | Sterile/<br>Non-Sterile | CE MARK DATE | GMDN CODE | GMDN CODE DESCRIPTION        |
|--------------|---|-------------------------|--------------|-----------|------------------------------|
| 93-5327      | Diamond Ball Tip @ 2.1mm, smooth, short | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5329      | Diamond Ball Tip @ 3.3mm, smooth, short | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5331      | Diamond Ball Tip @ 4.2mm, smooth, short | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5333      | Diamond Ball Tip @ 5.0mm, smooth, short | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5335      | Diamond Ball Tip @ 6.0mm, smooth, short | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5361      | Neuro Cutter, @ 1.8mm, short            | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5367      | Drill Cutter, @ 1.5mm, short            | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5369      | Drill Cutter, @ 2.0mm, short            | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5383      | Flame Shape Cutter @ 6.0mm, short       | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5384      | Flame Shape Cutter @ 7.5mm, short       | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5385      | Flame Shape Cutter @ 9.5mm, short       | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5386      | Boring Toole @ 6.0mm, short             | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5387      | Boring 93-5363Toole @ 9.1mm, short      | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5394      | Pin Cutter @ 1.0mm, short               | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5402      | Fluted Ball Tip Cutter @ 1.5mm, medium  | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5403      | Fluted Ball Tip Cutter @ 2.4mm, medium  | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5405      | Fluted Ball Tip Cutter @ 3.2mm, medium  | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5406      | Fluted Ball Tip Cutter @ 4.0mm, medium  | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5407      | Fluted Ball Tip Cutter @ 4.8mm, medium  | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5408      | Fluted Ball Tip Cutter @ 5.4mm, medium  | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5410      | Fluted Ball Tip Cutter @ 6.4mm, medium  | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5411      | Fluted Ball Tip Cutter @ 7.0mm, medium  | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5412      | Fluted Ball Tip Cutter @                | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand                 |

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|--------------|--|-------------------------|-----------------|--------------|------------------------------|
|              | 7.9mm, medium                                  |                         |                 |              | drill, reusable              |
| 93-5415      | Fluted Ball Tip Cutter @ 3.2mm, Omni-E, medium | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5417      | Fluted Ball Tip Cutter @ 4.8mm, Omni-E, medium | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5420      | Fluted Ball Tip Cutter @ 6.4mm, Omni-E, medium | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5422      | Fluted Ball Tip Cutter @ 7.9mm, Omni-E, medium | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5423      | Diamond Ball Tip @ 1.0mm, smooth, medium       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5425      | Diamond Ball Tip @ 1.5mm, smooth, medium       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5427      | Diamond Ball Tip @ 2.1mm, smooth, medium       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5428      | Diamond Ball Tip @ 2.7mm, smooth, medium       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5429      | Diamond Ball Tip @ 3.3mm, smooth, medium       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5430      | Diamond Ball Tip @ 3.8mm, smooth, medium       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5431      | Diamond Ball Tip @ 4.2mm, smooth, medium       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5433      | Diamond Ball Tip @ 5.0mm, smooth, medium       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5435      | Diamond Ball Tip @ 6.0mm, smooth, medium       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5448      | Diamond Ball Tip @ 2.7mm, rough, medium        | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5449      | Diamond Ball Tip @ 3.3mm, rough, medium        | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5450      | Diamond Ball Tip @ 3.8mm, rough, medium        | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5451      | Diamond Ball Tip @ 4.2mm, rough, medium        | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5452      | Diamond Ball Tip @ 4.6mm, rough, medium        | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5453      | Diamond Ball Tip @ 5.0mm, rough, medium        | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5455      | Diamond Ball Tip @ 6.0mm, rough, medium        | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5461      | Neuro Cutter @ 1.8mm, medium                   | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5463      | Neuro Cutter @ 3mm, medium                     | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |

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|--------------|---|-------------------------|-----------------|--------------|---------------------------------|
| 93-5465      | Neuro Cutter @ 3.0mm,<br>diamond, medium      | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5467      | Drill Cutter @ 1.5mm,<br>medium               | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5469      | Drill Cutter @ 2.0mm,<br>medium               | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5471      | Drill Cutter @ .8mm, depth<br>4.8mm, medium   | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5473      | Drill Cutter @ 1.0mm, depth<br>5.0mm, medium  | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5477      | Drill Cutter @ 1.5mm, depth<br>4.0mm, medium  | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5480      | Fluted Router, pointed, blade<br>19mm, medium | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5483      | Flame Shape Cutter @<br>6.0mm, medium         | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5484      | Flame Shape Cutter @<br>7.5mm, medium         | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5485      | Flame Shape Cutter @<br>9.5mm, medium         | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5486      | Boring Tool @ 6.0mm,<br>medium                | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5487      | Boring Tool @ 9.1mm,<br>medium                | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5493      | Diamond Cone Cutter @<br>5.0mm, rough, medium | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5494      | Pin Cutter @ 1.0mm, medium                    | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5495      | Diamond Disc @ 25mm,<br>medium                | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5501      | Fluted Ball Tip Cutter @<br>1.0mm, long       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5502      | Fluted Ball Tip Cutter @<br>1.5mm, long       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5503      | Fluted Ball Tip Cutter @<br>2.4mm, long       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5505      | Fluted Ball Tip Cutter @<br>3.2mm, long       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5506      | Fluted Ball Tip Cutter @<br>4.0mm, long       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5507      | Fluted Ball Tip Cutter @<br>4.8mm, long       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5510      | Fluted Ball Tip Cutter @<br>6.4mm, long       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |

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Number: WI-190003

Revision: 6

CO Number: 103018819

Type: Non PPE

Class: Work Instruction

Release Level: Production

ET-500 Rev. H

| PRODUCT CODE | DESCRIPTION  | Sterile/<br>Non-Sterile | CE MARK<br>DATE | GMDN<br>CODE | GMDN CODE<br>DESCRIPTION     |
|--------------|--|-------------------------|-----------------|--------------|------------------------------|
| 93-5512      | Fluted Ball Tip Cutter @ 7.9mm, long                       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5523      | Diamond Ball Tip @ 1.0mm, smooth, long                     | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5525      | Diamond Ball Tip @ 1.5mm, smooth, long                     | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5527      | Diamond Ball Tip @ 2.1mm, smooth, long                     | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5528      | Diamond Ball Tip @ 2.7mm, smooth, long                     | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5530      | Diamond Ball Tip @ 3.8mm, smooth, long                     | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5531      | Diamond Ball Tip @ 4.2mm, smooth, long                     | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5533      | Diamond Ball Tip @ 5.0mm, smooth, long                     | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5535      | Diamond Ball Tip @ 6.0mm, smooth, long                     | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5548      | Diamond Ball Tip @ 2.7mm, rough, long                      | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5549      | Diamond Ball Tip @ 3.3mm, rough, long                      | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5550      | Diamond Ball Tip @ 3.8mm, rough, long                      | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5551      | Diamond Ball Tip @ 4.2mm, rough, long                      | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5561      | Neuro Cutter @ 1.8mm, long                                 | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5563      | Neuro Cutter @ 3.0mm, long                                 | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5567      | Drill Cutter @ 1.5mm, long                                 | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5587      | Cutter for Use with Neurosurgical High Speed Drill Systems | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5593      | Diamond Cone Cutter @ 5.0mm, rough, long                   | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5605      | Fluted Ball Tip Cutter @ 3.2mm, medium XL                  | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5623      | Diamond Ball Tip @ 1.0mm, smooth, medium XL                | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5625      | Diamond Ball Tip @ 1.5mm, smooth, medium XL                | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5627      | Diamond Ball Tip @ 2.1mm, smooth, medium XL                | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |

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|--------------|---|-------------------------|--------------|-----------|------------------------------|
| 93-5628      | Diamond Ball Tip @ 2.7mm, smooth, medium XL | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5629      | Diamond Ball Tip @ 3.3mm, smooth, medium XL | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5631      | Diamond Ball Tip @ 4.2mm, smooth, medium XL | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5632      | Diamond Ball Tip @ 4.6mm, smooth, medium XL | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5648      | Diamond Ball Tip @ 2.7mm, rough, medium XL  | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5650      | Diamond Ball Tip @ 3.8mm, rough, medium XL  | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5693      | Diamond Cone Cutter @ 5.0mm, rough, medium  | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5702      | Fluted Ball Tip Cutter @ 1.5mm, long XL     | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5703      | Fluted Ball Tip Cutter @ 2.4mm, long XL     | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5705      | Fluted Ball Tip Cutter @ 3.2mm, long XL     | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5725      | Diamond Ball Tip @ 1.5mm, smooth, long XL   | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5727      | Diamond Ball Tip @ 2.1mm, smooth, long XL   | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5728      | Diamond Ball Tip @ 2.7mm, smooth, long XL   | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5729      | Diamond Ball Tip @ 3.3mm, smooth, long XL   | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5748      | Diamond Ball Tip @ 2.7mm, rough, long XL    | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5749      | Diamond Ball Tip @ 3.3mm, rough, long XL    | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5793      | Diamond Cone Cutter @ 5.0mm, rough, long XL | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5811      | Craniotome Cutter, spiral blade, short      | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5813      | Craniotome Cutter, spiral blade, medium     | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5815      | Craniotome Cutter, spiral blade, long       | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5821      | Craniotome Cutter, spiral blade, small      | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5823      | Craniotome Cutter, spiral blade, medium     | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand drill, reusable |
| 93-5825      | Craniotome Cutter, spiral                   | Non-Sterile             | 23-Mar-1999  | 46279     | Cranial hand                 |



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Release Level: Production

ET-500 Rev. H

| PRODUCT CODE | DESCRIPTION                      | Sterile/<br>Non-Sterile | CE MARK<br>DATE | GMDN<br>CODE | GMDN CODE<br>DESCRIPTION     |
|--------------|----------------------------------|-------------------------|-----------------|--------------|------------------------------|
|              | blade, long                      |                         |                 |              | drill, reusable              |
| 93-5900      | M-33 Round @ 6mm 8 blades/Z      | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5901      | AM-33 Round @ 6mm 8 blades/Z     | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5902      | M-35 Round @ 5mm 8 blades/Z      | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5903      | AM-35 Round @ 5mm 8 blades/Z     | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5904      | M-32 Round @ 7.5mm 10 blades/Z   | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5905      | AN-32 Round @ 7.5mm 10 blades/Z  | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5906      | AM-31 Round @ 9.2mm 12 blades/Z  | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5907      | M-3 Bud @ 6mm 8 blades/Z         | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5908      | AM-3 Bud @ 6mm 8 blades/Z        | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5909      | M-2 Bud @ 7.5mm 8 blades/Z       | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5910      | AM-2 Bud @ 7.5mm 8 blades/Z      | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5911      | M-1 Bud @ 9mm 8 blades/Z         | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5912      | A-2 Cyl Round @ 2.3mm 2 blades   | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5913      | M-8 Cyl. Round @ 3mm 2 blades/Z  | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5914      | AM-8 Cyl. Round @ 3mm 2 blades/Z | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5915      | B-1 Bone cutter @ 1.8mm          | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5917      | C-1 Bone cutter @ 1.1mm          | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5918      | S-1 Bone cutter @ 2.2mm          | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5919      | M-10 Bone cutter @ 2.24mm        | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5920      | AM-10 Bone cutter @ 2.24mm/Z     | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5921      | M-18 Cylinder @ 9.5mm/Z          | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |
| 93-5922      | M-17 Cylinder @ 12.5mm/Z         | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand drill, reusable |

Title: DECLARATION OF CONFORMITY – Appendix 2

Number: WI-190003

Revision: 6

CO Number: 103018819

Type: Non PPE

Class: Work Instruction

Release Level: Production

ET-500 Rev. H

| PRODUCT CODE | DESCRIPTION                      | Sterile/<br>Non-Sterile | CE MARK<br>DATE | GMDN<br>CODE | GMDN CODE<br>DESCRIPTION        |
|--------------|----------------------------------|-------------------------|-----------------|--------------|---------------------------------|
| 93-5923      | M-18 H Hollow Burr @<br>12.3mm/Z | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5924      | M-12 Cylinder @ 4.85mm           | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5925      | AM-12 Cylinder @ 4.85mm/Z        | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5926      | AM-9 Cylinder @ 5mm/Z            | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5927      | M-52 Cyl. Round @ 3.1mm/Z        | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5928      | M-8D Cyl. Round @ 3mm/Z          | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |
| 93-5929      | WH-1 Diameter Disc @<br>25mm     | Non-Sterile             | 23-Mar-1999     | 46279        | Cranial hand<br>drill, reusable |