

**DECLARATION OF CONFORMITY****We, Clement Clarke International Limited,**

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Declare under our sole responsibility that the product(s) listed below to which this declaration relates, is in conformity with the applicable provisions of Directive 93/42/EEC, Annex VII.

**Refer to page 2 of this document for a complete list of part codes and descriptions.**

**DEVICE GROUP:** MOUTHPIECES

**DESCRIPTION:** Various

**CLASSIFICATION:** The device(s) has been classified as class I, in accordance with Annex IX, essential requirements of the Council Directive 93/42/EEC.

**MDD CLASSIFICATION:** **Class I**  
**Rule 5** – invasive device with respect to a body orifice, transient use, non-active medical device.

**UMDNS Code & Term:** 15965 - Flowmeters, Pulmonary Function

**GMDN Number & Term:** 44545 – Breathing Mouthpiece, Single Use  
43467 – Breathing mouthpiece, reusable

**Refer to Harmonised Standards HSCCI20181105 for a complete list of applied standards.**

**EU Authorised Rep:** HAAG-STREIT SURGICAL GmbH & Co. KG  
Rosengarten 10  
22880 Wedel, Germany

Authorised By:

Signed:  .....

Mr G Ostacchini  
Group QA/RA Manager  
On Behalf of;  
Clement Clarke International Ltd  
Edinburgh Way, Harlow  
Essex, CM20 2TT  
United Kingdom

Date:  Dec 2020 .....



**Product Schedule**

| Description                                       | Quantity | Part Code  | GMDN  | UMDNS | GTIN              |
|---------------------------------------------------|----------|------------|-------|-------|-------------------|
| <b>Two Way Mouthpiece, Disposable</b>             |          |            |       |       |                   |
| Disp MP's,in dispenser                            | 5X20     | 3125030    | 44545 | 15965 | 0502 3323 0178 88 |
| Adult Printed M/piece                             | 500      | 3122003    | 44545 | 15965 | 0502 3323 0004 77 |
| Disp Paed M/PS in dispenser                       | 40       | 3125005    | 44545 | 15965 | 0502 3323 0178 71 |
| Paediatric M/piece                                | 500      | 3123030    | 44545 | 15965 | 0502 3323 0014 05 |
| <b>One Way Valve Mouthpiece, Disposable</b>       |          |            |       |       |                   |
| One Way Valve: EXP                                | 5X20     | 3122062    | 44545 | 15965 | 0502 3323 0012 45 |
| One Way Valve EXP                                 | 200      | 3122064    | 44545 | 15965 | 0502 3323 0004 91 |
| One Way Valve EXP                                 | 500      | 3122066    | 44545 | 15965 | 0502 3323 0013 44 |
| One Way Valve inspiratory                         | 5x20     | 3122061    | 44545 | 15965 | 0502 3323 0010 85 |
| One Way Valve inspiratory                         | 200      | 3122063    | 44545 | 15965 | 0502 3323 0005 07 |
| One Way Valve inspiratory                         | 500      | 3122065    | 44545 | 15965 | 0502 3323 0011 91 |
| In-Check Dial G16                                 | 1        | 3109300    | 44545 | 15965 | 0502 3323 0253 71 |
| In-Check Dial G16 (ATM)                           | 1        | 3109300ATM | 44545 | 15965 | 0502 3323 0253 88 |
| <b>Universal Mouthpiece, Single Use</b>           |          |            |       |       |                   |
| Universal M/piece in bag                          | 1        | 3103051    | 43467 | 15965 | 0502 3323 0015 28 |
| Universal M/piece in Bag x15                      | 15       | 3103095    | 43467 | 15965 | 0502 3323 0011 60 |
| AFS Mouthpiece in bag                             | 1        | 3104049    | 43467 | 15965 | 0502 3323 0168 50 |
| In-Check M                                        | 1        | 3109831    | 43467 | 15965 | 0502 3323 0008 04 |
| <b>Accessories</b>                                |          |            |       |       |                   |
| Restrictive Adaptor T (Turbohaler Mk II)          | 1        | 3109781    | N/A   | 15965 | 0502 3323 0010 47 |
| Restrictive Adaptor H (Handihaler)                | 1        | 3109859    | N/A   | 15965 | 0502 3323 0002 17 |
| Restrictive Adaptor D4 (Diskhaler 4 Blister)      | 1        | 3109788    | N/A   | 15965 | 0502 3323 0172 39 |
| Restrictive Adaptor C (Clickhaler)                | 1        | 3109786    | N/A   | 15965 | 0502 3323 0002 00 |
| Restrictive Adaptor G (Genuair)                   | 1        | 3109861    | N/A   | 15965 | 0502 3323 0173 45 |
| Restrictive Adaptor B/F (Breezhaler)              | 1        | 3109783    | N/A   | 15965 | 0502 3323 0171 92 |
| Restrictive Adaptor EH (Easyhaler M, Monotherapy) | 1        | 3109787    | N/A   | 15965 | 0502 3323 0172 22 |
| Restrictive Adaptor AAD,L (Accuhaler)44           | 1        | 3109822    | N/A   | 15965 | 0502 3323 0172 84 |
| O:W:VAL:PAED:M/PCE:ADAPT:PK 20 (OWV)              | 20       | 3122120    | 44545 | 15965 | 0502 3323 0012 07 |
| Mouthpiece Adaptor in polybag (Two Way)           | 1        | 3105019    | 44545 | 15965 | 0502 3323 0170 62 |