



**Manufacturer**  
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### Declaration of Conformity Class I Self-Certified

**To:** We the Manufacturer declares, under our sole responsibility that the products described below to which the technical documentation applies, complies with the applicable provisions of the safety & performance principles and the classification rules before being shipped. Furthermore, that they are in compliance with Annex II & III of the Medical Device Regulation 2017/745.

**Note:** List of actual devices covered under this declaration are attached below.

**Classification (MDR, Annex VII .....Class I as per rule 5)**

|                                           |                                                                                                                                                                                                         |                                                                                                                                    |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|
| <b>Ortho Arch SRN:</b><br>US-MF-000008544 | <b>Authorized European Representative shall be:</b>                                                                                                                                                     | <b>ISO Registration:</b>                                                                                                           |
| <b>UDI-DI Base:</b> D909                  | Emergo Europe<br>Prinsessegracht 20<br>2514 AP The Hague<br>The Netherlands<br>Tel: (31) (0) 70 345-8570<br>Email: <a href="mailto:EmergoEurope@ul.com">EmergoEurope@ul.com</a><br>SRN: NL-AR-000000116 | BSI<br>Kitemark Court, Davy Avenue<br>Knowlhill, Milton Keynes<br>MK5 8PP, UK<br>ISO Cert No.: MD 668843<br>Expiration: 2024-01-04 |

This declaration is based on the implementation of a Quality Management System certified for compliance to EN ISO13485:2016 in addition to compliance with harmonized standards EN ISO 14971:2019, BS EN ISO 15223-1: 2016, IEC 62336-1:2015 AMD 1:2020.

The Technical file is maintained at the manufacture's location.

*Jonathan Leng*  
**Signed**  
**Regulatory Manager**  
**Name: Jonathan Leng**

**Date 2022 February 2<sup>nd</sup>**

| Product # | GMDN Classification Name                     | Product Description                                        | GMDN Code | Rule | UDI-DI           |
|-----------|----------------------------------------------|------------------------------------------------------------|-----------|------|------------------|
| 550-104   | Orthodontic chin cap/cup                     | REPLACEMENT PADS FOR MULTI ADJUSTABLE FACEMASK             | 41067     | 5    | *+D90955010401*  |
| 600-755   | Hand-held dental retractor                   | LIP RING GREEN (5 PACK)                                    | 13380     | 5    | *+D9096007551A*  |
| 600-757   | Hand-held dental retractor                   | LIP RING WHITE (5 PACK)                                    | 13380     | 5    | *+D9096007571C*  |
| 600-759   | Hand-held dental retractor                   | LIP RING BLUE (5 PACK)                                     | 13380     | 5    | *+D9096007591E*  |
| 700-001   | Dental mould                                 | WIRE BONDER LG TIPS & HANDLE (10 TIPS)                     | 42344     | 5    | *+D9097000011_*  |
| 700-002   | Dental material application tool, single-use | BONDER HANDLE                                              | 35697     | 5    | *+D9097000020_*  |
| 700-004   | Dental mould                                 | BUTTON BONDER TIPS AND HANDLE (10 TIPS)                    | 42344     | 5    | *+D9097000041+*  |
| 700-007   | Dental mould                                 | POSTERIOR MOLAR PAD TIPS & HANDLE (10 TIPS)                | 42344     | 5    | *+D90970000711*  |
| 700-009   | Dental mould                                 | WIRE BONDER SMALL TIPS & HANDLE (10 TIPS)                  | 42344     | 5    | *+D90970000913*  |
| 700-011   | Dental mould                                 | BRACKET BONDER TIPS & HANDLE (10 TIPS)                     | 42344     | 5    | *+D90970001115*  |
| 600-760   | Hand-held dental retractor                   | LIP RING MIXED (5 PACK)                                    | 13380     | 5    | *+D90960076016*  |
| 700-100M+ | Dental mould                                 | MINI MOLD STARTER KIT 30 TIPS                              | 42344     | 5    | *+D909700100M2I* |
| 700-101   | Dental mould                                 | MINI MOLD INTRO KIT                                        | 42344     | 5    | *+D9097001012/*  |
| 700-102   | Dental mould                                 | MINI MOLD UNIVERSAL BITE OPENING KIT                       | 42344     | 5    | *+D9097001022+*  |
| 700-111   | Dental mould                                 | MINI MOLD PEG LATERAL 4 TIP KIT                            | 42344     | 5    | *+D9097001112+*  |
| 700-116   | Dental mould                                 | HABIT CONTROL TIPS & HANDLES (10 TIPS)                     | 42344     | 5    | *+D909700111612* |
| 700-117   | Dental mould                                 | ANTERIOR BITE RAMP 3MM TIPS & HANDLE (8)                   | 42344     | 5    | *+D90970011713*  |
| 700-117L  | Dental mould                                 | ANTERIOR BITE RAMP 5MM TIPS & HANDLE (8)                   | 42344     | 5    | *+D909700117L10* |
| 700-118   | Dental mould                                 | MINI MOLD HOOK BONDER TIPS & HANDLE (10)                   | 42344     | 5    | *+D90970011814*  |
| 700-119   | Dental mould                                 | CUSPID BITE RAMP ADULT TIPS & HANDLE (8)                   | 42344     | 5    | *+D90970011915*  |
| 700-119S  | Dental mould                                 | CUSPID BITE RAMP PEDO TIPS & HANDLE (8)                    | 42344     | 5    | *+D909700119S1X* |
| 700-123   | Dental mould                                 | MINI MOLD TUBE BONDER TIPS & HANDLE (10)                   | 42344     | 5    | *+D90970012310*  |
| 700-104   | Orthodontic appliance relief material        | PATIENT RELIEF WAX                                         | 45251     | 5    | *+D9097001041%*  |
| 700-204   | Orthodontic appliance relief material        | BRACE GARD SILICONE SQUARES (80)                           | 45251     | 5    | *+D90970020410*  |
| 700-205   | Dental mould                                 | CARTON OF PATIENT PACK 4 ORTHODOTS (24 PACKS)              | 42344     | 5    | *+D90970020511*  |
| 700-220   | Dental impression tray, single-use           | DISPOSABLE ORTHO IMPRESSION TRAYS UP SIZE 1 RED (10)       | 16350     | 5    | *+D9097002201+*  |
| 700-222   | Dental impression tray, single-use           | DISPOSABLE ORTHO IMPRESSION TRAYS LO SIZE 1 RED (10)       | 16350     | 5    | *+D90970022210*  |
| 700-224   | Dental impression tray, single-use           | DISPOSABLE ORTHO IMPRESSION TRAYS UP SIZE 2 ORANGE (10)    | 16350     | 5    | *+D90970022412*  |
| 700-226   | Dental impression tray, single-use           | DISPOSABLE ORTHO IMPRESSION TRAYS LO SIZE 2 ORANGE (10)    | 16350     | 5    | *+D90970022614*  |
| 700-228   | Dental impression tray, single-use           | DISPOSABLE ORTHO IMPRESSION TRAYS UP SIZE 3 BLUE (10)      | 16350     | 5    | *+D90970022816*  |
| 700-230   | Dental impression tray, single-use           | DISPOSABLE ORTHO IMPRESSION TRAYS LO SIZE 3 BLUE (10)      | 16350     | 5    | *+D9097002301%*  |
| 700-232   | Dental impression tray, single-use           | DISPOSABLE ORTHO IMPRESSION TRAYS UP SIZE 4 GREEN (10)     | 16350     | 5    | *+D90970023211*  |
| 700-234   | Dental impression tray, single-use           | DISPOSABLE ORTHO IMPRESSION TRAYS LO SIZE 4 GREEN (10)     | 16350     | 5    | *+D90970023413*  |
| 700-236   | Dental impression tray, single-use           | DISPOSABLE ORTHO IMPRESSION TRAYS UP SIZE 5 YELLOW (10)    | 16350     | 5    | *+D90970023615*  |
| 700-238   | Dental impression tray, single-use           | DISPOSABLE ORTHO IMPRESSION TRAYS LO SIZE 5 YELLOW (10)    | 16350     | 5    | *+D90970023817*  |
| 700-240   | Dental impression tray, single-use           | DISPOSABLE ORTHO IMPRESSION TRAYS UP SIZE 6 PURPLE (10)    | 16350     | 5    | *+D90970024010*  |
| 700-242   | Dental impression tray, single-use           | DISPOSABLE ORTHO IMPRESSION TRAYS LO SIZE 6 PURPLE (10)    | 16350     | 5    | *+D90970024212*  |
| 700-250   | Dental impression tray, single-use           | DISPOSABLE ORTHO IMPRESSION TRAYS MIXED PACK (3EA SIZE, 36 | 16350     | 5    | *+D90970025022*  |
| 800-026   |                                              | ELASTIC ATTACHERS ASSORTED COLORS (100)                    |           | 5    | *+D90980002613*  |
| 800-446   |                                              | Arch Markers (100)                                         |           | 5    | *+D90980044619*  |