

Declaration of Conformity

| PRODUCT IDENTIFICATION | | |
|----------------------------|---|---|
| Type | Product name | Model/number |
| Positioning and organizing | ChinStrap | N784, N785, N786, N787 |
| | EZCare Softouch | N9105BL, N9105CO, N9105PK, N9105TN, N9106BL, N9106CO, N9106PK, N9106TN, N9107BL, N9107CO, N9107PK, N9107TN, N9108BL, N9108CO, N9108PK, N9108TN, N9109BL, N9109CO, N9109PK, N9109TN, N9110BL, N9110CO, N9110PK, N9110TN, N9111BL, N9111CO, N9111PK, N9111TN, N926, |
| | NeoPulse | N781, N782, N783 |
| | NeoSeal | N420, N421, N422 |
| | NeoGrip | N601, N602, N602P, N602B, N602R, N602G, N602Y, N602O, N602V, N602A, N603 |
| | NeoBar | N709, N710, N711, N712, N712+, N713, N713+, N714, N714+, N715F, N715H, N716F, N716H, N718, N719N |
| Adhesives | EZ-Hold | N756, N757, N758 |
| | NeoSmile | N731 |
| | Hold-A-Line | N705 |
| | NeoBridge | N700, N701, N702 |
| | SoftSil | N745 |
| | NeoBond, NeoShape | N741, N742, N7426 |
| Suctioning / Accessories | Little Sucker, Little Sucker cover, NeoSucker Curved, Suction Caddy | N204, N204TP, N204C, N205, N205C, N205TP, N215, N224, N224TP, N225, N225TP, N206, N207, N208, N245 |
| | Meconium Aspirator | N0101, N0102 |
| Fabric Foam | NeoShades | N720, N721, N722, N724, N725, N726, N727, N728, N729, |
| Electrode | NeoLead | N300, N300CE, N301, N305, N305CE, N305CE-BRY, N306, N306CE, N315 |
| Active | NeoGlo | N555BL, N555AQ, N555VL, N555BP, N555PK, N555WH, N555SL, N555BK |

| MANUFACTURER | | |
|------------------------|--|-----------------------|
| Name of company | Address | Representative |
| Neotech Products LLC | 28430 Witherspoon PKWY Valencia, CA 91355 USA | Leo Arya |

| AUTHORIZED REPRESENTATIVE | | |
|----------------------------------|--|--|
| Name of company | Address | Telephone/email |
| Emergo Europe | Prinsessegracht 20 2514 AP The Hague The Netherlands | +31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com |

| CONFORMITY ASSESSMENT | | |
|--|---|--------------------------|
| Device classification | Route to compliance | Standards applied |
| Class I Annex IX, Rule 1 except the active device to be under rule 12 and suction tips to be under rule 5 | Annex VII of MDD 93/42/EEC Council Directive | ISO 13485:2016 |

Neotech Products LLC declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.



Craig McCrary
President
03/13/2019