# EC Declaration of Conformity

We, manufacturer **Widex A/S**
**Nymoellevej 6**
**DK-3540 Lynge**
**Denmark**

Declare under our sole responsibility that the following **PRODUCTS** starting with Serial no. 10.000

Brand: Bloom

Description: Hearing Aid

| Model | Variant(s) | Type | GMDN code | GMDN Term |
|---|---|---|---|---|
| BFP U | T-VC-RC | BTE | 34671 | Behind-the-ear air-conduction hearing aid |
| BFM U | RC | | | |
| BPA U | RC | RIC | 47169 | Receiver-in-canal air-conduction hearing aid |
| BFS U | T-RC | RIC, RITE | | |
| BXP U | T-RC | ITE | 34672 | In-the-ear air-conduction hearing aid |

are in conformity with the essential requirements and other applicable provisions of the following **EU Directives**:

**Council Directive 93/42/EEC as amended by Dir. 2007/47/EC (MDD)**
**Directive 2014/53/EU (RED)**
**Directive 2011/65/EU (RoHS 2)**

| | |
|---|---|
| Conformity assessment procedure | MDD : Annex II of 93/42/EEC<br>RED : Annex II of 2014/53/EU |
| Notified Body | MDD : TÜV SÜD Product Service GmbH, Notified Body No.: NB 0123<br>Ridlerstr. 65, 80339 München, Germany |
| EC-Certificate | MDD : No. G1 093461 0011 |
| Classification of Device | MDD : Class IIa, Rule 9 according to 93/42/EEC Annex IX |
| Applied standards and specifications in conformity assessment.<br>Standard versions valid on the date when this DoC is issued. | MDD : EN 1041, EN 10993-1, EN 13485, EN 14155, EN 14971, ISO 15223-1, EN 50419, EN 60118-0, EN 60118-6, EN 60118-7, EN 60118-13, EN 60601-1-2, EN 62366<br>RED : EN 60950-1, EN 62479, EN 301 489-1, EN 301 489-3, EN 300 330<br>RoHS 2 : EN 50581, EN 62321 |

Lynge, 24-09-2020
Place and date of issue

Senior Director, Global Regulatory Affairs Kristine Klitgaard Pedersen