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## ***Declaration of Conformity***

We

**3M Poland Manufacturing Sp. z o.o.  
ul. Kwidzyńska 6  
51-416 Wrocław  
Poland**

hereby declare under our sole responsibility that the CE marked products,  
to which this declaration relates,

**Orthoptic eye patches:**

### **OPTICLUDE**

**1537/20, 1537/50, 1537/100, 1537M-50, 1537M-100, 1537T  
2537PE, 2537PF, 2537MPE  
2537M D PG-50, 2537M D PB-100, 2537M D PG-100,  
1538M-50, 1538M-100, 2538PE, 2538MPE,  
2538M D PB-50, 2538M D PG-50, 2538M D PB-100, 2538M D PG-100, 2538M P-50 Disney Edition NL,  
1539/20, 1539/50, 1539/100, 1539M-50, 1539M-100, 1539T,  
2539PE, 2539PF, 2539MPE  
2539M D PB-100, 2539M D PG-100, 2539M P-50 Disney Edition NL**

### **Nexcare OPTICLUDE**

**NE-OPT6250, NE-OPT8257, 1537, 1539**

are classified, according to rule 1 of Annex IX of the  
Medical Device Directive 93/42/EEC, as **Class I non-sterile** devices  
and

are in accordance with

***Annex VII and all other applicable provisions  
of the Directive 93/42/EEC,***

on the approximation of the laws of the European Union Member States  
concerning medical devices.

Signature: *Aneta Górka*  
Aneta Górka  
Management Representative

Date: *5.06.2019*

relating to REG-STED-05-131830

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