

MD



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## Classification of MD acc MDD 93/42/EEC Annex IX

### Product: Hearing Instruments/Hearing Aids System

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Part of process: **PRODUCT DEFINITION**

#### Conclusion:

Product Category	MD Class:	Classification Rule:
Hearing aids (BTE, ITE, CRT, CIC, MIC, IIC)	Class IIa	Rule 5, 9
Hearing aids Software: - Firmware (FW) - Fitting Software - Standalone software (SSW)	Class IIa Class IIa	II. IMPLEMENTING RULES 2. Implementing rules Rule 2.3.

#### Classification acc. FDA regulation:

Product Category	MD Class:	Product code
Non wireless Hearing aids incl. FW and SSW (BTE, ITE, CRT, CIC, MIC, IIC)	Class 1, 510(k) exempt	ESD
Wireless Hearing aids incl. FW and SSW (BTE, ITE, CRT, CIC, MIC, IIC)	Class 2, 510(k) exempt	OSM
Hearing aids with Tinnitus masker feature	Class 2, 510(k)	KLW

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