g.tec medical engineering GmbH
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Konformitätserklärung
Declaration of Conformity

Product details:

Product name	**g.Nautilus PRO / g.Nautilus PRO Sahara and components**
Type	**8, 16, 32 -Channel Wireless Amplifier dry and wet systems**
Order number	**5100PRO, 5200PRO, 5110PRO, 5210PRO, 5120PRO, 5220PRO, 5101PRO, 5201PRO, 5111PRO, 5211PRO, 5112PRO, 5212PRO**

Classification:

Safety class	**II (according to IEC 60601-1:2005)**
Type of applied part	**BF (according to IEC 60601-1:2005)**
Protection against mechanical distortion and liquids	**IP44 Headset (according to EN 60529)**
	IP40 Basestation (according to EN 60529)
Operation Mode	**S1 (permanent operation, according to IEC 60601-1:2005)**

Certificates:

Quality Management System	**EN ISO 13485:2012 + AC:2012 for medical device Manufacturer**
Certification Body	**TÜV SÜD Product Service GmbH**
Number of certificate	**Q1N 17 07 01232 001**

Used standards:

Harmonized standards	**EN 60601-1:2006+A1/2013**
	EN 60601-2-26:2015 (partly fulfilled)
	EN 60601-1-2:2007+AC2010
	EN ISO 14971:2012
	EN 62366:2008
	EN 62304:2006
	EN ISO 10993-1:2009

The manufacturer declares in sole responsibility that the device mentioned above under Product is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and are conform to harmonized standards of 93/42/EWG (Medical Device Directive) listed above.

g.Nautilus PRO produced under certified quality management system (ISO13485) and in conformity to Harmonized European standards can be considered as medical grade product. Additional components e.g. software for visualization and recording which completes the intended use are necessary to obtain a certification as a medical device.

CE

Schiedlberg, 09.11.2017
Validity 1 year

er,
Chief Executive Officer