



ADNV&MMKO
COMPANY

Presafe Denmark A/S

Product List

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The following products are covered by DGM - 512:

Product ID	Product	Class	Date for placing on the market (with CE Mark)	Product family on DGM-512 covering the device
	Standard Coils			
9016E0582	Coil C-100	IIa	2006-07-12	Magnetic Stimulation Coils
9016E0482	Coil C-B60	IIa	2006-07-12	Magnetic Stimulation Coils.
9016E0555	Coil MC-125	IIa	2006-07-12	Magnetic Stimulation Coils
9016E0462	Coil MC-B65-HO, 2m	IIa	2006-07-12	Magnetic Stimulation Coils
9016E0472	Coil MC-B65-HO, 8m	IIa	2006-07-12	Magnetic Stimulation Coils
9016E0564	Coil MC-B70	IIa	2006-07-12	Magnetic Stimulation Coils
9016E0573	Coil MMC-140	IIa	2006-07-12	Magnetic Stimulation Coils
9016E0631	Coil MMC-140-II	IIa	2006-09-12	Magnetic Stimulation Coils
9016E0641	Coil RT120	IIa	2007-06-21	Magnetic Stimulation Coils
9016E0651	Coil RT120-I	IIa	2007-06-21	Magnetic Stimulation Coils
9016E0431	Coil D-B80	IIa	2009-05-13	Magnetic Stimulation Coils
9016E0671	Coil MC-B35	IIa	2010-04-22	Magnetic Stimulation Coils
9016E0211	Coil MMC-90	IIa	2012-03-26	Magnetic Stimulation Coils
9016E0251	Coil MMC-140 A/P	IIa	2016-03-04	Magnetic Stimulation Coils
9016E0141	Coil C-B70	IIa	2020-01-22	Magnetic Stimulation Coils
	Coolod coils			
9016E0491	Coil Cool-B65	IIa	2006-07-12	Magnetic Stimulation Coils
9016E0221	Coil Cool B65 RO	IIa	2013-04-02	Magnetic Stimulation Coils
9016E0521	Coil Cool-B70	IIa	2010-11-15	Magnetic Stimulation Coils
9016E0501	Coil Cool-B65 A/P	IIa	2010-11-26	Magnetic Stimulation Coils
9016E0531	Coil Cool D-B80	IIa	2010-12-01	Magnetic Stimulation Coils
9016E0511	Coil Cool-125	IIa	2011-04-13	Magnetic Stimulation Coils
9016E0231	Coil Cool-B65 A/P RO	IIa	2013-09-13	Magnetic Stimulation Coils
9016E0681	Coil Cool-B35	IIa	2015-10-29	Magnetic Stimulation Coils
9016E0291	Coil Cool-050	IIa	2015-12-07	Magnetic Stimulation Coils
9016E0541	Coil Cool D-B80 A/P	IIa	2017-01-13	Magnetic Stimulation Coils
9016E0111	Coil Cool-835 HO	IIa	2016-05-20	Magnetic Stimulation Coils
9016E0101	Coil Cool-B35 RO	IIa	2016-01-08	Magnetic Stimulation Coils
9016E0151	Coil Cool-B65 CO	IIa	2019-11-05	Magnetic Stimulation Coils
9016E0161	Coil Cool-B65 A/P CO	IIa	2019-11-05	Magnetic Stimulation Coils
9016E0121	Coil Cool B70 A/P	IIa	2020-01-22	Magnetic Stimulation Coils
	MRi scanner coils			
9016E0661	Coil Mri-B91	IIa	2013-02-05	Magnetic Stimulation Coils
9016E0271	Coil Mri-B91 Air Cooled	IIa	2016-09-23	Magnetic Stimulation Coils
	Fluid cooled coils			
9016E0442	Coil MCF-75	IIa	2006-07-12	Magnetic Stimulation Coils
9016E0423	Coil MCF-B65	IIa	2006-07-12	Magnetic Stimulation Coils
9016E0413	Coil MCF-125	IIa	2006-07-12	Magnetic Stimulation Coils
9016E0401	Coil MCF-B70	IIa	2010-05-31	Magnetic Stimulation Coils
	Stimulator and monitors			
9016C0701	MEP Monitor	IIa	2006-07-12	MEP monitors

Certificate No: 10000463954-PA -NoMAON Rov a o
Piacca and dalo Hevi, 20 May 2021

Terms and conditions

The certificate is subject to the following terms and conditions;

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system, the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body Identification number.

End at Cerilicst

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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ICP4-5-11-MOD-2



ADNENHKO
COMPAAT

Presafe Denmark A/S

Product ID	Product	Class	Date for placing on the market (with CE Mark)	Product family on DGM-512 covering the device
9016E0852	MagPro Compact	Ila	2007-02-26	Magnetic stimulators
9016E0861	MagPro R20	Ila	2014-05-23	Magnetic stimulators
9016E0881	MagPro R20+	Ila	2020-12-21	Magnetic stimulators
9016E0721	MagPro R30	Ila	2006-07-12	Magnetic stimulators
9016E0741	MagPro R30 incl. MagOption	Ila	2006-07-12	Magnetic stimulators
9016E0771	MagPro R100	Ila	2006-10-25	Magnetic stimulators
9016E0711	MagPro X100	Ila	2006-07-12	Magnetic stimulators
9016E0731	MagPro X100 Ind <u>MagOption</u>	Ila	2006-07-12	Magnetic stimulators

"The products on this list have been accepted by Presafe Denmark A/S"

Date: 2021-05-19

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Name and signature: xxxxxxxxxxxxxx

Title: Lead auditor