

Urgent Field Safety Notice

Commercial name of the affected product: AMICA GEN

FSCA identifier: Af 27/17A

Type of action: Recall

Date: April, 11, 2017

Details on affected devices:

Recall Code: AP 27-17°

Generators codes to be recalled: AGN-H-1.0, AGN-3.0, AGN-R-1.0

Codes, lots and serial/number: see attached list.

Description of the problem:

After an internal AUDIT performed inside our Quality System, we verified that generators with s/n and lot number indicated could be not in compliance with our CE certification due to a Power Supply model installed with a trade mark different from the one certified.

We would like to ensure you that Electrical Safety tests accompanying the generators are valid and passed so there are no risks for patients or users .

At the moment, for precautional reasons, our Certified Body has temporarily put in stand-by our CE certification.

Advice on action to be taken by the users

For Hospitals and Distributors: identify and collect in quarantine all the listed units showed in present form.

Hospitals can contact the distributors to organize the generators shipment.

Distributors can contact the manufacturer to organize the generators shipment or can agree with manufacturer that both verification and replacement of the power unit should be performed in distributor house through authorized persons.

All the different actions can be implemented in ten days, but before shipping back the generators the CE certification must be re-activated from Notified Body.

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this to other organisation on which this action has an impact.

Contact Reference person:

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HS Hospital Service SpA

Sede legale/Registered Office: Via Zosuno, 13 - 00178 Roma, ITALY
Stabilimento di produzione/Facility: Via Angela Vacchi, 23/25- 04011 Aprilia (Latina), ITALY
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ATTACHMENT: LIST OF GENERATORS TO BE RECALLED

AGN H 1.0			
SN	LOTII	CLIENTE	PAESE
7	4975	LOGSA	Spagna
94	12874	VIRTUDE PALERMO	It alia
132	18923	LOGSA	Spagna
138	18924	MEDICOR	Germania
133	19024	CULPAN	Australia
144	19641	LOGSA	Spagna
145	19642	ABLATECH SARL	Francia
146	19875	GELISIM	Turchia
147	19876	The Surgic al company	Belgio
148	19877	ABLATECH SARL	Francia
149	19878	Hospita! Devices	Italia
150	20018	LOG5A	Spagna
151	20019	MEDICOR	Germania
152	20337	MEDICOR	Germania
153	20341	MEDICOR	Germania
154	20342	MEDICOR	Germania
155	20510	MEDICOR	Germania
156	20511	MEDICOR	Germania
157	20512	ABLATECH SARL	Francia
158	20614	MEDICOR	Germania
159	20615	ABLATECH SARL	Francia
160	20618	LOGSA	Spagna
161	20752	MEDICOR	Germania
162	20753	CULPAN	Australia
163	20997	OBEX	Nuova Zelanda
164	20998	MEDICOR	Germania
165	20999	CULPAN	Australia
166	21000	LOGSA	Spagna
167	21254	LOGSA	Spagna
168	21255	V.IVERIELI ENDOCRINOLOGY METABOLOGY CENTER	Georgia
169	21256	LOGSA	Spagna
170	21257	LOGSA	Spagna
173	21650	VIVAN VESTA	Iran
174	21653	VIVAN VESTA	Iran
175	21654	LOGSA	Spagna
177	21656	LOGSA	Spagna
178	21657	CULPAN	Aust ralia
182	22140	ASIAMED	Singapore
183	22141	MANATECH	Regno Unito
185	22143	PRAGMATIC	Finlandia
186	22144	MEDIFOR	Italia
189	22451	DAYMED	Ita lia
190	22452	DAYMED	Italia
191	22453	DAYMED	Italia
192	22454	DAYMED	Italia
193	22455	DAYMED	Italia
194	22578	ABLATECH SARL	Francia
195	22579	OBEX	Nuova Zelanda
196	22580	ATS	Egitto

HS Hospita(Service SpA

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SN	LOTII	CLIENTE	PAESE
301	23019	ATS	Egitto
305	26377	SELEFAR	Italia
198	23346	MEDIFOR	Italia
201	23680	MEDICOR	Germania
202	23681	MEDICOR	Germania
203	23682	MEDICOR	Germania
204	24218	ACCES MEDICAL	Tunisia
206	24220	ANGIOCARE	Paesi Bassi
215	24618	BIOTECH (NA)	Italia

AGN 3.0			
SN	LOTII	CLIENTE	PAESE
149	19025	HS MEDICAL INC	Stati Uniti
150	19248	HS MEDICAL INC	Stati Uniti
151	19249	HS M EDICAL INC	Stati Uniti
152	19522	HS M EDICAL INC	Stati Uniti
153	19523	HS M EDICAL INC	Stati Uniti
154	19550	HS MEDICAL INC	Stati Uniti
155	19551	HS MEDICAL INC	Stati Uniti
156	19552	MEDICOR	Germania
157	20619	ABLATECH SARL	Francia
158	20620	ABLATECH SARL	Francia
159	20621	MEDICOR	Germania
160	20622	VIVAN VESTA	Iran
161	20623	HS MEDICAL INC	Stati Uniti
162	21001	ABLATECH SARL	Francia
163	21002	HS M EDICAL INC	Stati Uniti
164	21260	HS M EDICAL INC	Stati Uniti
165	21261	ABLATECHSARL	Francia
166	21262	ABLATECH SARL	Francia
167	21263	M EDICOR	Germania
168	21716	ABLATECH SARL	Francia
169	21717	ABLATECH SARL	Francia
170	21718	ABLATECH SARL	Francia
171	21719	ABLATECH SARL	Francia
172	22028	ABLATECH SARL	Francia
173	22029	ABLATECH SARL	Francia
174	22030	ABLATECH SARL	Francia
175	22406	MEDICOR	Germania
176	22407	MEDICOR	Germania
177	22408	MANATECH	Regno Unito
178	22409	MANATECH	Regno Unito
179	22456	ATS MEDICAL	Egitto
180	22581	ATS M EDICAL	Egitto
181	22582	ATS M EDICAL	Egitto
182	22583	ABLATECH SARL	Francia
183	23208	ABLATECHSARL	Francia
186	23684	ATS M EDICAL	Egitto
187	23685	ATS MEDICAL	Egitto
315	22835	ATS MEDICAL	Egitto
316	22836	ATS MEDICAL	Egitto
317	22837	ABLATECH SARL	Francia

HS Hospital (Società a partecipazione paritetica)
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AGN- R 1.0			
SN	LOTII	CLIENTE	PAESE
137	18426	FOCUS	Grecia
140	18427	FOCUS	Grecia
147	22873	DAYMED	Italia

HS Hospital Service SpA

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