CA-MI srl
Via Ugo La Malfa 31, 43010 Pilastro (PR) ITALY
Tel. +39.0521.637133/631138 Fax +39.0521.639041
export@ca-mi.it - vendite@ca-mi.it - www.ca-mi.it

R.E.A. Di Parma n. 157757
Cod. Fisc. / Partita IVA e R.I. 00977090349
UE IDENTIFICATION CODE IT 00977090349
REGISTRO A.E.E. N° IT08020000000264
REGISTRO PILE E ACCUMULATORI N° IT 09060P00000971

CERTIFIED: ISO 9001 – ISO 13485

Pilastro (PR) - Italy, 14th April 2011

Object: SAFETY ADVICE (CA-MI ref. 22032001)
Volunteer recall of New Hospivac 400 medical device (surgical suction unit)

Dear Customer,

by the present letter we inform you that CA-MI S.r.l. started a volunteer recall of the New Hospivac 400 medical device in all its configurations (REF RE 410350/xx). The reason is a possible internal malfunctioning due to the fault of one of the outsourced electric component used in the device.

Our technical hypothesis for the fault condition is currently focusing on a defect of the CAPACITOR electric component. The electric component manufacturer (our supplier) might have had a problem during its production process, either in one single piece within a full lot, or in the full lot. If such a defect existed, a general technical fault of the device would take place. For this reason, we opted for a preventive and volunteer recall of the units.

We therefore inform you that we started the process of revision and recall of the lot numbers where the faulty capacitor has been used (see table “A”).
Moreover, as secondary and preventive action, we will proceed with the revision of the units, either at your premises or in our factory, with plant of a new condenser higher in resistance and in safety class. This second action will involve all devices manufactured until the end of November 2010 as a preventive countermeasure.
In fact, starting from December 2010 (from lot nos. 1012C01 on), we used a different capacitor in the New Hospivac 400 (we issued technical modification to solve such as problems). According to our investigations underway, this new capacitor is not involved by the same fault.

In both action events, CA-MI will manage directly and with collaboration of every customer, the possibility to revise directly devices at place, to reduce the closure time. Where possible, a Ca-MI’s technician or one of customer’s technician, trained and authorized from CA-MI, he will revise devices at place replacing faulty capacitor with a new one, all in compliance with service manual and instruction of CA-MI Quality Assurance.

Table A

Production Lot #	**Device Ref. #**
LOT 0909CA109	REF RE 410350
LOT 0909CA08	REF RE 410350
LOT 0910CA23	REF RE 410350/10
LOT 0910CA28	REF RE 410350/09
LOT 0909CA110	REF RE 410350/01
LOT 0910CA01	REF RE 410350/18
LOT 0907CA05	REF RE 410350/01
LOT 0906CA51	REF RE 410350
LOT 0905CA66	REF RE 410350/09
LOT 0905CA59	REF RE 410350/01
LOT 0910CA34	REF RE 410350
LOT 0907CA09	REF RE 410350/09
LOT 0909CA04	REF RE 410350/10
LOT 0907CA28	REF RE 410350/09

Production Lot #	Device Ref. #
LOT 0906CA27	REF RE 410350/18
LOT 0906CA26	REF RE 410350/01
LOT 0907CA27	REF RE 410350/10
LOT 0909CA103	REF RE 410350/10
LOT 0907CA25	REF RE 410350/18
LOT 0910CA35	REF RE 410350/01
LOT 0909CA03	REF RE 410350/01
LOT 0907CA42	REF RE 410350/09
LOT 0907CA64	REF RE 410350/09
LOT 0907CA47	REF RE 410350
LOT 0905CA64	REF RE 410350/05
LOT 0910CA31	REF RE 410350/10
LOT 0910CA26	REF RE 410350/18

Actions to be taken

1) Please check your stock as soon as possible. If you have devices with lot numbers as per Table “A”, please do not sell or use, inform CA-MI indicating Ref. # and Serial # and wait for our replacement or in loco repair action.
2) IMPORTANT: to comply with the 93/42/EEC MDD and subsequent changes, you shall revert the above communication to those customers who received from you one or more devices listed in Table “A”, according to your traceability procedure. Those customers, in turn, shall follow the same procedure suspending sales/use of the devices and inform you accordingly.
3) Because of professional destination use of this device and to avoid mistakes in the translation of technical concept/explanation, this document and all our further communication will be issued in English language. Please translate this communication in your country language and issue it to your direct customers on the market.

We kindly ask you to sign and return the enclosed form as a confirmation that you received this Safety Advice and you will follow the instructions contained in it.

[redacted] – Quality Assurance

Fax. 0521 639041 / Tel. 0521 631138
E-mail: tecnico@ca-mi.it

CA-MI S.r.l.
Via Ugo La Malfa, 31
43010 Pilastro di Langhirano (PR) Italy
Cod. Fisc. e Part. IVA 00977090349
Tel. +39 0521 637133 - +39 0521 631138
Fax +39 0521 639041
[redacted]

CA-MI srl
Via Ugo La Malfa 31, 43010 Pilastro (PR) ITALY
Tel. +39.0521.637133/631138 Fax +39.0521.639041
export@ca-mi.it - vendite@ca-mi.it - www.ca-mi.it

R.E.A. Di Parma n. 157757
Cod. Fisc. / Partita IVA e R.I. 00977090349
UE IDENTIFICATION CODE IT 00977090349
REGISTRO A.E.E. N° IT08020000000264
REGISTRO PILE E ACCUMULATORI N° IT 09060P00000971

CERTIFIED: ISO 9001 – ISO 13485

Pilastro, 30th March 2011

PLEASE RETURN THE PRESENT FORM
BY FAX (+39-0521-639-041)
OR BY EMAIL export@ca-mi.it

OBJ.: ACKNOWELDGEMENT OF RECEIPT OF SAFETY ADVICE

FSN N. CA-MI 01/2011 DATE: 30th March 2011	ITEM. NEW HOSPIVAC 400 – REF RE 410350/xx LOT Nos. – (see Safety Advice Email)
ISSUED BY: QUALITY ASSURANCE	
RECEIVED BY: ☐ FAX ☐ E-MAIL ☐ MAIL ☐ BY HAND ☐ OTHER…….	

☐ **The undersigned declares to have read and understood this communication**

COMPANY NAME:		
ADRESS:		
CITY':	COUNTRY:	ZIP CODE:
TEL:	FAX:	E-MAIL:

I hereby confirm that all units -including those shipped already to our customers- have been traced by us.

NOTES / REMARKS

NAME OF THE PERSON IN CHARGE: ……

DATE, SIGNATURE and STAMP .....