



ENTE CERTIFICAZIONE MACCHINE



# CERTIFICATE OF COMPLIANCE

**CERTIFICATE NR. T120613/SKM667**

MANUFACTURER:	
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WE CERTIFY THE FOLLOWING PRODUCT(S):

PRODUCT	MEDICAL MODELS
MODEL/S	KAR/ACLS8000, KAR/BLS, KAR/ALS, KAR/CPR, KAR/I, KAR/AED, KAR/G, KAR/GF, KAR/C, KAR/D, KAR/LV, KAR/L, KAR/CK, KAR/S, KAR/H, KAR/T, KAR/F, KAR/W, KAR/B, KAR/A, HLY
YEAR	2012

REMARK :

THIS DOCUMENT HAS BEEN ISSUED UPON A REVIEW OF THE DATASHEETS AND OF THE TECHNICAL CONSTRUCTION FILE.  
THE APPARATUS IS CONSIDERED TO MEET THE REQUIREMENTS OF THE BELOW STANDARDS, THEREFORE TO FULFIL THE  
REQUIREMENTS OF THE BELOW LISTED DIRECTIVES.

<b>93/42/EEC 2007/47/EC</b>	<b>MEDICAL DEVICES DIRECTIVE</b>
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<b>SAFETY STANDARDS EN NORMS:</b> EN 60601-1: 2006/AC: 2010, EN 60601-1-2: 2007/AC: 2010, EN 980: 2008, EN ISO 14971: 2009
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THIS DOCUMENT IS ONLY VALID FOR THE EQUIPMENT AND CONFIGURATION DESCRIBED AND IN CONJUNCTION WITH THE  
TEST DATA DETAILED ABOVE. NEVERTHELESS THE MANUFACTURER IS NOT EXEMPTED TO PERFORM ALL THE NECESSARY  
ACTIVITIES BEFORE ISSUING THE DECLARATION OF CONFORMITY. IN CASE THE APPLIANCE IS MODIFIED OR THE  
APPLIANCE WILL BE EQUIPPED WITH ACCESSORIES NOT SPECIFIED IN THE MANUFACTURER OPERATOR MANUAL, IT IS  
RECOMMENDED TO GET IN TOUCH WITH ENTE CERTIFICAZIONE MACCHINE FOR EC VALIDITY EXTENSION.

DATE OF ISSUE JUNE

AREA MANAGER  
LUCA BEDONNI



GENERAL MANAGER  
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