



ENTE CERTIFICAZIONE MACCHINE



ISO 9001



OHSAS 18001

# CERTIFICATE OF COMPLIANCE

**CERTIFICATE NR. T120521/GSE551**

MANUFACTURER:	
NAME	GUANGZHOU SWORDENTAL EQUIPMENT AND MATERIAL CO., LTD
ADDRESS	No.92 OF GANGKOU ROAD, SHILOU TOWN, PANYU DISTRICT, GUANGZHOU CITY, GUANGDONG PROVINCE, CHINA

WE CERTIFY THE FOLLOWING PRODUCT(S):

PRODUCT	<b>DIAMOND BURS</b>
MODEL/S	TF-11 ISO.173/014; TF-12 ISO.173/016; TF-13 ISO.173/018; TF-21 ISO.171/016; TR-12 ISO.199/016; TR-13 ISO.198/018; TR-14 ISO.198/022; TR-21 ISO.179/016; MS-13 ISO.299/016; TC-11 ISO.160/016; TC-21 ISO.160/014; FO-25 ISO.257/028; SF-11 ISO.111/012; SO-20 ISO.288/012; SR-11 ISO.141/012; RS-11 ISO.553/019; EX-21 ISO.237/012; BR-45 ISO.001/010; BR-30 ISO.001/023; CF-11 ISO.198/010; DI-42 ISO.019/014; SI-47 ISO.010/014; WR-13 ISO.068/042; CR-11 EFISO.196/019; CD-59F ISO.171/013
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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**SAFETY STANDARDS EN NORMS:**

**EN ISO 3823-1:1998, EN ISO 7711-3:2004, EN ISO 14971:2009**

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 MAY 2012**

AREA MANAGER  
LUCA BEDONNI



GENERAL MANAGER  
ANTONIO BEDONNI

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