



ENTE CERTIFICAZIONE MACCHINE



# CERTIFICATE OF COMPLIANCE

**CERTIFICATE NR. T120521/GSE551**

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

WE CERTIFY THE FOLLOWING PRODUCT(S):

<b>PRODUCT</b>	<b>DIAMOND BURS</b>
<b>MODEL/S</b>	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-11EFISO.196/019; CD-59F ISO.171/013
<b>YEAR</b>	<b>2012</b>

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>
---------------------------------	----------------------------------

<b>SAFETY STANDARDS EN NORMS: EN ISO 3823-1:1998, EN ISO 7711-3:2004, EN ISO 14971:2009</b>
---

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

**ENTE CERTIFICAZIONE MACCHINE S.R.L.**

VIA MINCIO,386 - 41056 SAVIGNANO S/P. (MO) - ITALY -

+39 059 763736 +39 059 766306 +39 059 761838 info@entecerma.it www.ENTECERMA.IT