

**INSTRUCTIONS FOR FILLING OUT AND SENDING THE FORM**

The office of the Italian Ministry of Health (MoH) responsible for checking forms cannot consider valid any documentation that is not completed in accordance with the indications listed below; if the form is incomplete, MoH will request further information.

**Directions:**

- This form must be sent in order to access the database of medical devices to register data relating to medical devices. For in vitro diagnostic medical devices and custom-made devices, different forms are required - please refer to the MoH website.
- Please specify the roles of the companies.
- Please attach to this form the document providing proof of identity of both legal representatives, which is legible and valid.
  - o In case of italian authorised company, it is required to upload this form in PDF format into the database of medical devices according to the directions laid down in the MoH website
  - o In case of foreign authorised company, it is required to send the form in PDF format, by email with the following subject line "Communication of authorisation for access and data entry in the medical devices database" to the following email address: [dgfdm@postacert.sanita.it](mailto:dgfdm@postacert.sanita.it)

Ministero della Salute  
Direzione Generale dei Dispositivi Medici e  
del Servizio Farmaceutico  
Ufficio 3  
PEC: [dgfdm@postacert.sanita.it](mailto:dgfdm@postacert.sanita.it)

**Subject:** *Communication of authorisation from the delegating company to the authorised company and appointment of the responsible person for entering and updating data in the database of the Ministry of Health and in the "Repertorio" of medical devices in Italy according to Ministerial Decree 21 December 2009.*

<p><b>Fields to be filled in by the DELEGATING company</b></p>	<p>The company <u>Orantech Inc.</u> VAT Number <u>91440300349737507E</u> with registered office in (please indicate the full address) <u>Zone#A,4F,1st Bld,7th Industrial Zone,Yulv Community, GongMing, Guangming New District, Shenzhen, Guangdong 518106, China</u> Phone number <u>+86-17722803207</u> e-mail <u>junfeng.wang@orantech.com</u> PEC-Electronic Certified E-mail (optional field) _____ for devices which will be registered in the database and possibly included in the medical device list called "Repertorio", acts as (<i>mark the applicable option with an X; more than one option can be selected</i>):  <ul style="list-style-type: none"><li><input type="checkbox"/> a) manufacturer, as defined in Article 1, paragraph 2, letter f) of Legislative Decree No 46 of 24 February 1997;</li><li><input type="checkbox"/> b) subject referred to in Article 12, paragraph 2 of Legislative Decree No 46 of 24 February 1997 (subjects who place systems or procedure packs on the market);</li><li><input type="checkbox"/> c) authorised representative in the EU designated by the manufacturer, referred to in Article 13, paragraph 2 of Legislative Decree No 46 of 24 February 1997.</li></ul><p>For the purpose of entering and updating data in the database of medical devices of the Italian Ministry of Health, the <u>legal representative</u> of the delegating company Name <u>Liming</u></p></p>
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Surname	Xue		
Born in	China	on	Mar.27 <sup>th</sup> .1966
Tax code (*)	91440300349737507E		
email	junfeng.wang@orantech.com		

### AUTHORISES

the following company to carry out the registration and communication of information within the database of medical devices of the Italian Ministry of Health according to the obligations set out in art. 13 of Legislative Decree No 46 of 24 February 1997

<p><i>Fields for AUTHORISED and REGISTRANT company registering information within the database</i></p>	<p>the company <u>Medival S.r.l.</u></p> <p>Tax Code or VAT Number <u>VAT Number IT01630000287</u></p> <p>with registered office in (indicate the full address) <u>Via San Crispino 33 – 35129 Padova Italy</u></p> <p>Phone number <u>049 775477</u></p> <p>e-mail <u>katia.giraldo@medival.it</u></p> <p>PEC-Electronic Certified E-mail (optional field) _____</p> <p>which, for the devices that will be registered in the database and possibly included in the medical device list called “Repertorio”, acts as (<i>mark the applicable option with an X; more than one option can be selected</i>):</p> <p class="list-item">a) manufacturer, as defined in Article 1, paragraph 2, letter f) of Legislative Decree No 46 of 24 February 1997;</p> <p class="list-item">b) subject referred to in Article 12, paragraph 2 of Legislative Decree No 46 of 24 February 1997 (subjects who place systems or procedure packs on the market);</p> <p class="list-item">c) authorised representative in the EU designated by the manufacturer, referred to in Article 13, paragraph 2 of Legislative Decree No 46 of 24 February 1997.</p> <p><input checked="" type="checkbox"/> company validly authorised by the subjects referred to in letters a, b or c.</p> <p>Therefore, for the purpose of entering data in the database of medical devices of the Ministry of Health, the <u>legal representative</u> of the authorised and registrant company</p> <p>Name <u>Andrea</u></p> <p>Surname <u>De Benetti Valeggia</u></p> <p>Born in <u>Padova</u> on <u>April 29<sup>th</sup>, 1969</u></p>
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Tax code (\*) DBNNDR69D29G224L

email AValeggia@medival.it

**APPOINTS THE FOLLOWING AS RESPONSIBLE FOR DATA COMMUNICATION ACCORDING TO THE  
MINISTERIAL DECREE 21 DECEMBER 2009**

d) himself/herself  
 employee of the authorised and registrant company

*If you have selected "employee of the authorised and registrant company", please provide the employee's signature and details:*

Name Katia

Surname Giraldo

Born in Monselice on December 23th, 1972

Tax code (\*) GRLKTA72T63F382B

email katia.giraldo@medival.it

*Date*

*Signature of the legal representative of the delegating company*  
**ORANTECH, INC**  
深圳市橙汇科技有限公司

*Wu Ming Xue*

*.....*  
*Authorized Signature(s)*

*Signature of the legal representative of the authorised company*

*Signature of the employee of the authorised company*

**Attachments – copy of identity documents which are currently valid and contain the handwritten signatures of the legal representatives of both companies**

*(\*) If the subject does not have an Italian tax code, please indicate a unique identifier valid in the country of origin*

姓名 薛黎明

性别 男 民族 汉

出生 1966 年 3 月 27 日

住址 广东省深圳市南山区工业  
七路30号华采花园南海阁  
7C



公民身份证号码 310104196603270490



中华人民共和国  
居民身份证

签发机关 深圳市公安局南山分局

有效期限 2014.11.19-长期

*Liming Xue*