



S.F.C. sas di Sandro Fossi e C.  
Quality Consulting

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# Company Profile

© S.F.C. sas di Sandro Fossi e C.  
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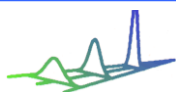


S.F.C. was founded in 1995 by Sandro Fossi to better serve his experience and skills in the field of medical devices.

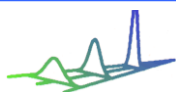
Sandro Fossi obtained his degree in Physics *magna cum laude* at the University of Florence in 1976. Before starting S.F.C., Fossi has been working for several multinational companies in the fields of advanced electronics and medical devices, collecting a significant experience in software development for embedded systems, medical devices, project management, and regulatory affairs.

We specialize in supporting small and large organizations in setting up Quality Management Systems (ISO 9001, ISO 13485) and managing regulatory issues (CE marking, FDA, etc.)

A list of main references is attached.



Company	Field	Tasks	Cert. Or Notified Body
Ab medica A.p.A. Lainate (MI)	Medical Devices	CE Marking (93/42(EEC) Italian Repertoire Registration	0123
Active Implants Ltd Israel	Implantable Medical Devices	Italian Repertoire Registration	0474
AMID Advanced Medical Imaging Srl Sulmona (AQ)	Medical Imaging Software	CE Marking (93/42(EEC) FDA Premarket notification	0051
Azienda USL 11 Empoli-Valdera – Servizio di Tecnologie Sanitarie	Clinical Engineering	UNI EN ISO 9001:2000	DNV
Bracco Imaging S.p.A.	Medical Software	CE Marking (93/42(EEC))	-
Bristol Myers-Squibb Divisione ConvaTec S.r.l. (Roma)	Medical Devices	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Italian Repertoire of Medical Devices	DNV
Bionen sas Firenze	Medical Devices for electrophysiology	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 CE Marking Italian Repertoire of Medical Devices	IMQ - 0051
CABEL Srl Pistoia	Medical Devices	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 CE Marking (93/42(EEC))	IMQ - 0051
Ebit AET S.p.A. Genova-Firenze	Medical Information Technology	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 CE Marking	IMQ
EBNEURO S.p.A. Firenze-Verona	Biomedical electronics	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Annex II 93/42/EEC	IMQ - 0051
Esafarma s.a.s. Terontola di Cortona (AR)	Disposable Medical Devices	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Ann. II,V 93/42/EEC Italian Repertoire Registration	DNV- 0473
UNICARE Cavriglia (AR)	Disposable Medical Devices	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Ann. V 93/42/EEC Italian Repertoire Registration	Certitex ISS - 0373
Fe.Ma Srl Locate di Triulzi (MI)	Medical Devices	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Ann. II,V 93/42/EEC Italian Repertoire Registration	DNV - 0473
GAYMAR Inc. USA	Medical Devices	Italian Repertoire Registration	-
ICO Guanti S.p.A. Genova-Milano	Medical Devices	CE Marking (93/42(EEC))	-



Company	Field	Tasks	Cert. Or Notified Body
Luigi Salvadori S.p.A. Scandicci (FI)	Medication medical devices	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Ann. II,V 93/42/EEC Italian Repertoire Registration	0373
ME.TE.C. S.r.l. Cavriglia (AR)	Medical Devices	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Ann. V 93/42/EEC	0373
Media Lab Software La Spezia	Medical imaging software	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Ann. II,V 93/42/EEC Italian Repertoire Registration	current
MON&TEX S.p.A. Calenzano (FI)	Medical Devices	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Ann. II,V 93/42/EEC Italian Repertoire Registration	0373
Moretti S.r.l. S. Giovanni Valdarno (AR)	Medical devices	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Ann. II,V 93/42/EEC Italian Repertoire Registration	DNV
SALVAMED SA Sandanski (Bulgaria)	Medication	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Ann. II,V 93/42/EEC Italian Repertoire Registration	0373
SELOM S.p.A. Genova	Cleaning and Sterilization services	CE Marking Annex V	0373
Servizi Italia S.p.A. Montecchio Precalcino (VI), Trieste	Cleaning and Sterilization services	CE Marking Annex V	0373
Servizi Ospedalieri S.p.A. Gruppo Manuencoop Ferrara	Cleaning and Sterilization services	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Ann. II,V 93/42/EEC Italian Repertoire Registration	0473
S.O.F. Servizi Ospedalieri Fiorentini S.p.A. Firenze	Cleaning and Sterilization services	Ann. V 93/42/EEC	0373
Titanox Srl Torre de' Picenardi (CR)	Medical Devices for sterilization	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Annex V 93/42/EEC Italian Repertoire Registration	0473
Vannini Dental Industry S.r.l. Grassina (FI)	Dental medical devices	UNI EN ISO 9001:2000 UNI EN ISO 13485:2004 Ann. VII 93/42/EEC Italian Repertoire Registration	BV
W.L. Gore e Associati S.r.l. Cavaion Veronese (VR)	Medical Devices in EPTFE ( <i>Gore-Tex</i> ®)	UNI EN ISO 9001:2000 Italian Repertoire Registration	DNV
Welcare Industries S.p.A. Orvieto (TR)	Medical Devices	Annex V 93/42/EEC	0459