



Certificate

The SQS herewith attests that the organisation named below has a management system that meets the requirements of the normative basis mentioned.



Nuova Ompi S.r.l. Unipersonale
Via Molinella, 17
35017 Piombino Dese (PD)
Italy

Certified sites according to appendix

Scope

Provision of laboratory services for chemical, chemical-physical and biological characterization of pharmaceutical packaging, medical devices, parts making up medical devices of combined products

Normative basis

EN ISO 13485:2016 Medical devices – Quality Management System

Reg. no. H52654
Page 1 of 2

Validity 11.06.2024 – 10.06.2027
Issue 11.06.2024


A. Grisard, President SQS


F. Müller, CEO



Swiss Association for Quality and Management Systems (SQS)
Bernstrasse 103, 3052 Zollikofen, Switzerland



Nuova Ompi S.r.l. Unipersonale

Via Molinella, 17
35017 Piombino Dese (PD)
Italy

Central function	Scope	Norm / Revision	Reg. no.	Validity
Nuova Ompi S.r.l. Unipersonale Via Molinella, 17 35017 Piombino Dese (PD) Italy	Provision of laboratory services for chemical, chemical-physical and biological characterization of pharmaceutical packaging, medical devices, parts making up medical devices of combined products	EN ISO 13485:2016	H52654	11.06.2024 10.06.2027
Locations	Scope	Norm / Revision	Reg. no.	Validity
Ompi of America Inc. 451 D St., Suite 704 Boston, MA 02210 United States of America	US TEC - Provision of laboratory services for chemical, chemical-physical and biological characterization of pharmaceutical packaging, medical devices, parts making up medical devices of combined products	EN ISO 13485:2016	H52654	11.06.2024 10.06.2027
Nuova Ompi S.r.l. Unipersonale Via Molinella, 17 35017 Piombino Dese (PD) Italy	EMEA TEC Analytics - Provision of laboratory services for chemical, chemical-physical and biological characterization of pharmaceutical packaging, medical devices, parts making up medical devices of combined products	EN ISO 13485:2016	H52654	11.06.2024 10.06.2027
Nuova Ompi S.r.l. Unipersonale Via Molinella, 17 35017 Piombino Dese (PD) Italy	EMEA TEC Advanced Technology - Provision of laboratory services for chemical, chemical-physical and biological characterization of pharmaceutical packaging, medical devices, parts making up medical devices of combined products	EN ISO 13485:2016	H52654	11.06.2024 10.06.2027

Reg. no. H52654
Page 2 of 2

Validity 11.06.2024 – 10.06.2027
Issue 11.06.2024

The validity of this appendix depends on the validity of the main certificate.


A. Grisard, President SQS


F. Müller, CEO



Swiss Association for Quality and Management Systems (SQS)
Bernstrasse 103, 3052 Zollikofen, Switzerland

