

Certificate of Approval

This is to certify that the Management System of:

SOFMEDICA HELLAS MEDICAL TECHNOLOGY S.A.

131, Kifisias Avenue, Marousi, 151 24 Athens, Greece

has been approved by LRQA to the following standards:

EN ISO 13485:2016

Approval number(s): ISO 13485 – 00036057

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

The scope of this approval is applicable to:

Marketing, sales & tender participation, import, storage, distribution of innovative life-saving medical devices and technologies and related spare parts. Technical support (installation, checking and preventive maintenance, emergency interventions, diagnosis, repairs, delivery and installation of spare parts). Clinical support and training for related medical devices and equipment. Provision and translation of the information supplied by the manufacturer (instructions for use and labels) and changing the pack size in order to market the medical devices.

Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA France SAS

for and on behalf of: LRQA Limited



Certificate Schedule

| Location | Activities |
|--|--|
| <p><u>Head Office:</u> 131, Kifisias Avenue, Marousi, 151 24 Athens, Greece</p> | <p>EN ISO 13485:2016 Marketing, sales & tender participation, import, storage, distribution of innovative life-saving medical devices and technologies and related spare parts. Technical support (installation, checking and preventive maintenance, emergency interventions, diagnosis, repairs, delivery and installation of spare parts). Clinical support and training for related medical devices and equipment. Provision and translation of the information supplied by the manufacturer (instructions for use and labels) and changing the pack size in order to market the medical devices.</p> |
| <p><u>Warehouse:</u> 119, Kifisias Avenue, Marousi, 151 24 Athens, Greece</p> | <p>EN ISO 13485:2016 Marketing, sales & tender participation, import, storage, distribution of innovative life-saving medical devices and technologies and related spare parts. Technical support (installation, checking and preventive maintenance, emergency interventions, diagnosis, repairs, delivery and installation of spare parts). Clinical support and training for related medical devices and equipment. Provision and translation of the information supplied by the manufacturer (instructions for use and labels) and changing the pack size in order to market the medical devices.</p> |

