

quality assurance & regulatory affairs agreement

regarding norms EN 62304 / IEC 62304

(Life Cycle Requirements for Medical Device Software / Medical Device Software Life Cycle Processes)

and norms EN 14971 / ISO 14971 (Risk Management of Medical Products)

between: h/p/cosmos sports & medical gmbh, Am Sportplatz 8, DE 83365 Nussdorf-Traunstein / Germany

and: **enter your company name and address and contact details**

responsibilities / task / subject	contact person @ company name	contact person @ h/p/cosmos
Quality Management Representative (QMB)	name	Mr. Michael Heser
Quality Assurance Manager	name	Mr. Michael Heser
Regulatory Affairs Manager	name	Mr. Michael Heser
Safety Officer for Medical Devices Europe: medical device vigilance system / notifiable incident reporting system / USA: Medical Device Reporting (MDR) System	name	Mr. Michael Heser
R&D Research & Development Manager	name	Mr. Franz Harrer
Production Manager	name	Adrian Ried / Michael Heser
Service Manager	name	Mr. Richard Schmidt
Purchase Manager	name	Mr. Ferdinand Bäurle

For staying in compliance with the medical device directive MDD (directive 93/42/EEC + 2007/47/EC) both parties agree to:

- inform each other before each party makes amendments on interface and/or software which can have safety related impact on the treadmill control. The same clause applies for other safety related parts & components.
- perform and exchange tests and test protocols on interface and/or software which can have safety related impact on the treadmill control. **b1)** With electronic data logger all commands between the systems (treadmill and host equipment/software) via coscom protocol are saved, printed, documentation will be exchanged and analyzed by both parties. **b2)** Checksum and Acknowledgement have to be implemented in the interface protocol accordingly. **b3)** Error simulation on failsafe function (timeout simulation of broken RS232 interface cable or PC failure or software crash) and with "status communication" of stop button pressed on the treadmill have to be made. **b4)** If "stop" button was pressed on the treadmill, also the load protocol on the host PC-Software or system has to stop and must not continue to send speed or elevation commands automatically. See [implementation notes](#) on [coscom.org](#)
- have internal documented and implemented bugfixing process for medical device software maintenance.
- observe and inform each other in case of any amendment in the risk management status and/or regulatory affairs status and/or notifiable incident status and/or clinical data and post market surveillance (PMS) status.
- exchange and report any kind of information of clinical studies, data and assessments that are related to h/p/cosmos devices as part of a market surveillance process. Both parties are obliged to set up internal procedures in order to assure the bi-directional reporting system for such a complaint handling and vigilance reporting and the exchange of market surveillance data.
- exchange and report any malfunction or deterioration in the characteristics and/or performance of the h/p/cosmos device (including a report about the incident and serial number of the device) within 10 days (or earlier if applicable in some countries), as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health.
- record the serial numbers and end users names and addresses of all h/p/cosmos machines sold to customers and save those for at least 15 years or over the life time of the respective product. This is for organizing mailings in the unlikely event of product recalls.
- allow access for the notified bodies to quality and safety and regulatory affairs related documents.
- archive quality and safety related documents for at least 15 years or for the expected lifetime of the product plus 5 years.
- note: medical treadmills, used also for stress testing, are risk class IIb active diagnostic and active therapeutic devices.

These agreement clauses cover their medical devices and software where both parties are involved. The archiving and information clauses are valid even after termination of an active sales and purchase co-operation.

place, date: _____ place, date: _____

signature: h/p/cosmos sports & medical gmbh
Franz Harrer - President & CEO / R & D Manager

signature: **company name**
authorized signatory name -President & CEO-