quality assurance & regulatory affairs agreement | coscom v3 | coscom v4

regarding standards EN 62304 / IEC 62304, directives 93/42/EEC, MDD Medical Device Directive, medical device regulation MDR
(Life Cycle Requirements for Medical Device Software / Medical Device Software Life Cycle Processes)
and standards EN 14971 / ISO 14971 (Risk Management of Medical Products)

between: h/p/cosmos sports & medical gmbh, Am Sportplatz 8, DE 83365 Nussdorf-Traunstein / Germany eMail: r&d@hpcosmos.com
and:

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

For staying in compliance with safety related issues, the MDD and the MDR on the interface communications and linkage of medical devices both parties agree to:

a) inform each other in writing 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.
b) perform & exchange tests & test protocols on interface and/or software which can have safety related impact on the treadmill and/or ergometer control.
b1) With electronic data logger all commands between the systems (treadmill/ergometer and host equipment/software) via coscom v3 or coscom v4 protocol are saved and documentation will be exchanged and analyzed, verified, validated and archived 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 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 and/or ergometer, 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 v3 or v4 on http://www.coscom.org
c) have internal documented and implemented bug-fixing process for medical device software maintenance during entire software life-cycle.
d) observe and inform each other in case of any amendment in the risk management status and/or regulatory affairs status, adverse event reporting and/or notifiable incident status and/or clinical data and post market surveillance (PMS) status.
e) 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 related to the coscom interface control functions, features and safety.
f) Vigilance system: 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.
g) record the serial numbers and end users names & addresses of all h/p/cosmos machines sold to customers & 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 or field corrective actions or warning messages.
h) allow access for the responsible notified bodies and authorities to quality and safety and regulatory affairs related documents and to the premises also for audits and unannounced audits where applicable.
i) archive quality and safety related documents for at least 15 years or for the expected lifetime of the product plus 5 years.
j) inform each other in case of any changes of scope or invalidity on the quality assurance certification (eg. EC or ISO 13485 certificates)
k) note: medical treadmills, used also for stress testing, are risk class IIb active diagnostic and active therapeutic devices.
l) note: connecting two or more medical devices will create a medical system and has to be treated and documented as a new medical device/system also via risk assessment and management process accordingly.

These agreement clauses cover their sports and/or 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:

signature: h/p/cosmos sports & medical gmbh
Franz Harrer – Managing Director -

place, date:

signature:
- Managing Director -

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