EC CERTIFICATE

PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE

(Annex V of the directive 93/42/EEC on medical devices)

45 40 01

issued to

Qualisys AB
Kvarnbergsgatan 2
SE-411 05 GÖTEBORG

Sweden

We hereby certify that the Quality System of

Qualisys AB

for production, final inspection and marketing of

motion capture systems

which are medical devices in class IM, has been assessed with respect to the conformity assessment procedure described in Article 11.2 (c) and Annex V of Council Directive 93/42/EEC on Medical Devices, as latest amended by Council Directive 2007/47/EC, and found to comply with the requirements.

The Council Directive 93/42/EEC is implemented in Swedish Law by the national regulation LVFS 2003:11, as latest amended by LVFS 2013:11.

This certificate applies to activities performed at
Kvarnbergsgatan 2, SE-411 05 GÖTEBORG, Sweden

This certificate was originally issued on 20th May 2016 and remains valid until 19th May 2021 provided that the conditions connected to this certificate are fulfilled

SP Technical Research Institute of Sweden
Certification - Notified Body No. 0402

Signed by: Lennart Aronsson
Reason: I have approved this document
Date & Time: 2016-05-20 15:23:30 +02:00

Lennart Aronsson
Certification Manager

Reason: I am the author of this document
Date & Time: 2016-05-27 09:03:20 +02:00

Karin Andresen
Certification Officer

SP Technical Research Institute of Sweden
Box 857, SE-501 15 Borås, Sweden
Phone: +46 10-516 50 00
E-mail/internet: info@sp.se/www.sp.se

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Conditions

Validity

The certificate will remain valid until the expiry date, and allows the holder to use SPs notified body identification number 0402 in conjunction with the CE-mark, on products covered by this certificate, provided that the conditions stated below are fulfilled:

- that surveillance audits are performed, with approved result;
- that the company notifies SP on all modifications on the products, and that the company does not apply the CE-mark to any new or modified products without confirmation from SP;
- that the company notifies SP on all significant changes in the quality system, in its activities and/or organization
- that the certificate is not used in a misleading manner, e.g. in marketing activities.
- that the company notifies SP about vigilance actions, if any.

Basis for certificate

- The documentation presented has been examined and assessed by SP in accordance with LVFS 2003:11, as amended by LVFS 2013:11, annex 5, item 3.2.
- An initial audit and follow-up audits of the quality system at the company's premises in Göteborg has been performed by SP.
- SP file 5P04459.

Surveillance

SP will perform surveillance inspections to ensure that the company maintains and applies the quality system that is subject of the certificate.
In accordance with the EU Commission recommendations of 2013-09-24, there will also be unannounced audits during the three year period. These audits can be performed at the manufacturers as well as at selected crucial supplier's premises.

Miscellaneous

Additional conditions appear in "Terms and conditions for audit and assessment of management systems as notified body" and in Agreement concerning continuous inspection between Fogless International AB and SP.

Certificate history

Issue	Date	Activity
1	20th May 2016	Certificate issued

Register of products covered by the certificate

Designation	Article number	Classification
Qualisys Clinical Systems (including Oqus and Miqus cameras, compatible hardware and related software)	1504XX (XX = 01 u.i. 99)	IM

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