Press Release / April 14, 2015

Method Park successfully certified according to the medical standard DIN EN ISO 13485

After nearly one year preparation time for the audit by the TÜV Rheinland (Rhineland Technical Inspection Association) the Method Park Engineering GmbH has now been officially certified according to DIN EN ISO 13485:2012. With this official certification by an independent authority the Method Park customers from the medical technology sector can rely on the compliance of the company's quality management system and development processes with the most stringent regulatory requirements.

With this certification Method Park meets the increasing quality requirements of the industry. In the aftermath of the tightening of European Directives, numerous manufacturers of medical equipment increasingly demand proof of certified quality management from their business partners.

"With certification according to DIN EN ISO 13485:2012 we have shown ourselves to be a competent and reliable partner for medical technology. At the same time, we reinforce the trust that our customers place in our services", says Dr. Martin Geier, Managing Director of the Method Park Engineering GmbH, with satisfaction. The Erlangen-based company can, for example, now include the autonomous standard-compliant development of parts for medical products in its services portfolio.

Once again Dr. Geier: "Of course we will continue to further develop our quality standards in order to further improve the efficiency of our processes and so be ready to face the challenges of the future."

At Method Park, Quality Management has always been of the highest priority. The Method Park company group has been certified according DIN EN ISO 9001 since 2007 and regularly carries out recertification audits.

DIN EN ISO 13485 defines the harmonized regulatory requirements for the Quality Management system of medical product manufacturers. As an internationally recognized standard, this standard formulates guidelines for the design and development, production, installation, maintenance and marketing of medical products. The ongoing improvement of the quality of products and services is the uppermost goal. The DIN EN ISO 13485 standard is based largely on the structure of DIN EN ISO 9001, but also includes a number of specific requirements for the medical product sector in addition to the requirements of DIN EN ISO 9001, such as in regard to risk management, traceability, sterile manufacturing conditions and product recall.

About Method Park

For many years Method Park has successfully offered consulting in questions of software for safety-critical systems in the automotive industry and in the medical technology area, for which the company develops its own software solutions. Method Park brings extensive know-how to fields with high and extremely high safety requirements. With this knowledge Method Park offers its customers a variety of solutions from a single source that contribute to the success of each company.

Method Park is the competent partner for consulting, coaching, training, engineering services and products for all questions of software development processes. The "Stages" Web-based process management portal developed by Method Park supports users with the practical implementation of development processes. Stages ensures the realization of predefined quality standards and process models and can be integrated in all common development environments.

Furthermore, Stages enables the global distribution of development tasks beyond corporate boundaries.

Founded in Erlangen in 2001, Method Park employs around 125 persons at sites in Erlangen, Munich and Stuttgart, as well as in Detroit and Miami in the USA.

TÜVRheinland

Zertifikat

Die Zertifizierungsstelle der
TÜV Rheinland LGA Products GmbH

bescheinigt, dass die Organisation

Method Park Engineering GmbH
Wetterkreuz 19 a
91058 Erlangen
Deutschland

für den Geltungsbereich:

Design und Entwicklung von kundenspezifischer Software im Bereich Medizintechnik

ein Qualitätsmanagementsystem für Medizinprodukte eingeführt hat und anwendet.

Der Nachweis wurde erbracht, dass die Forderungen der

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

erfüllt sind. Das Qualitätsmanagementsystem unterliegt einer jährlichen Überwachung.

Dieses Zertifikat ist gültig ab:	2015-03-24
Zertifikat-Registrier-Nr.:	SX 60099013 0001
Ein Audit wurde durchgeführt, Bericht Nr.:	21209902 002
Dieses Zertifikat ist gültig bis:	2018-03-18

Zertifizierungsstelle

DAkkS Deutsche Akkreditierungsstelle D-ZM-14165-01-02

Datum 2015-03-24

Dipl.-Ing. I. Monker

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