MPI MEDICOPLAST International GmbH

Produktion und Vertrieb medizinischer Einweggeräte

***Confirmation***

We confirm that our sterilization equipment

is maintained
is controlled
is calibrated

in accordance to our internal requirements, basing on the normative standards described in DIN EN ISO 11135:2007 (annex C).
Regular inspections, basing on ISO standards, have been carried out by our Notified Body MedCert. In January 2014 we have changed the Notified Body from MedCert to QS Zürich. The new certificate is available on the MEDICOPLAST homepage (www.medicoplast.de).

We confirm that no significant changes in the physical profiles of the sterilization chamber, the preconditioning- and degassing chamber or the sterilization process itself appeared in 2013. A repetition of the commissioning will be done frequently every 3 years or in case of significant changes.

The customers will be informed in case of activities which can cause an effect on the validation of their processes and products.

Regarding routine cycles MP01, MP02, MP03 and MP06, no changes of the process parameters took place.

C Hoff

Dr. Christiane Hoffmann
Dipl. Biol.
Director of Sterilization

Illingen, the 26th of February 2014

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Illingen, the 26th of February 2014