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MEDICAL DEVICES: Guidance document

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HOMOGENEOUS BATCHES

„Homogeneity of production batches“

Certain statistical verification procedures are only meaningful when batches, (lots), are homogeneous.

A batch is considered homogeneous when equivalent parts or materials are manufactured and/or tested in the same manner, without interruption, typically on the same day or in the same time period, and produced by the same person, or with the same machine/equipment set-up and fulfil the same specifications.

For IVD's and certain other medical devices, such as dental material the following complementary definition shall apply: Mixtures of substances such as reagents aliquoted from the same bulk mixture are considered homogeneous if the mixing and aliquoted processes are validated.

Note: In ISO 2859, „lot“ is defined similar to „homogeneous batch“ of this paper.

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