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Comparison:

	CE marked products	NON-CE marked products
Intended use	Therapeutic application (methadone program)	No therapeutic use (proof of abuse)
Product design including sample collector	see technical file	identical to CE product
Analytical sensitivity (detection limits)	see instructions for use	identical to CE product
Analytical specificity	see instructions for use	identical to CE product
Cross-reactivity	see instructions for use	identical to CE product
Manufacturing process	see technical file	identical to CE product
Quality control	see technical file	identical to CE product
Batch stability	see QC data	identical to CE product
Storage of the test	see instructions for use and labels	identical to CE product
Handling the test	see instructions for use	identical to CE product
Certification of the product	Certification by notified body	no certification required
Registration of the product	Registration in DMIDS	no registration needed
Performance monitoring in the field	according to the rules of the IVDR	included in the surveillance of the CE product
Labeling, packaging, disposal	see instructions for use and labels	identical to CE product, except CE label

Important: CE-marked in vitro diagnostics are intended exclusively for medical use!