

Good Laboratory Practice (GLP)

Assay	ISO / IEC 17025	GLP
Cytotoxicity acc. to ISO 10993-5 & USP 87		
MTT	+	+
XTT	+	+
Neutral red	+	+
Agar diffusion test	+	+
BCA	+	+
LDH	+	+
ATP	+	-
Irritation acc. to ISO 10993-23		
EpiDerm™ (in vitro, intact skin model)	+	+
EpiAirway™	+	+
EpiIntestinal™	+	+
EpiNasal™	+	+
EpiOral™	+	+
EpiVaginal™	+	+
EpiOcular™	+	+
Patch test on 30 volunteers	+	-
Genotoxicity acc. to ISO 10993-3		
Full Ames Test	+	+
Ames II Screening	+	+
Micronucleus Test	+	+
Mouse Lymphoma Assay	+	-
Sensitization acc. to ISO 10993-10		
KeratiNoSens™	+	+
h-CLAT	+	+
kDPRA	+	+
Endotoxins & Pyrogenicity		
Monocyte Activation Test	+	-
Endotoxins – LAL-Test	+	-
Hemocompatibility Test acc. to ISO 10993-4		
Dynamic or static: Hemolysis, Platelet counts, Leucocyte activation, Complement activation, PTT	+	-

Assay	ISO / IEC 17025	GLP
Reprocessing of Medical Devices		
Simulated Use (AAMI ST98)	+	-
Manual Cleaning Validation – Protein and TOC residues (acc. to AAMI ST98 / ISO 15883-5)	+	+
Automated Cleaning Validation – Protein and TOC residues (acc. to AAMI ST98 / ISO 15883-5)	+	+
TOC as residual contamination from production processes (acc. to ISO 19227)	+	-
Purity of products and implants after production – ISO 19227	+	-
Manual Disinfection Validation MDR and FDA	+	-
Automated Disinfection Validation of thermolabile products MDR and FDA	+	-
Steam Sterilization Validation for Medical Devices Sterilizability Assessment (acc. to ISO 17664-1, ISO 13060, ISO 17665)	+	+
Drying Efficacy of Sterilization Processes	+	-
Bioburden of Medical Devices (ISO 11737-1)	+	-
Sterility of Medical Devices (ISO 11737-2)	+	+
Accelerated Aging of Medical Devices for Shelf Life Determination (ASTM F1980)	+	-
Material Resistance to Disinfectants (ISO 21530)	+	-
End of Life Simulations (e.g. up to 2000 reprocessing cycles)	+	-
Testing of the sterile barrier and shelf life in accordance with ASTM F1980	+	-
Testing of the sterile barrier performance of porous materials and containers (exposure chamber) – ASTM F 1608 and ISO 11607	+	-



Contact us –

We look forward to work with you.

HygCen Germany GmbH –

Trust in over 30 years of lab experience.