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3.4 Compatibility, Biocompatibility

Biocompatibility tests were carried out based on


- DIN EN ISO 10993-5
- DIN EN ISO 10993-10

Following table includes materials of Disposable sensors with patient skin contact, related test reports including evaluations referred to biocompatibility.

Part	Specification	Test report	Biokompatibilität
Double coated inner tape	3M Double Coated Medical Tape 1509 (Polyethylene) Manufacturer: 3M Medical Specialities	Product Clinical Data Summary (2010)	PASS
Single coated strain relief tape, (Infant, Neonatal)	3M Single Coated Medical Tape 1525L (Polyethylene) Manufacturer: 3M Medical Specialities	Product Clinical Data Summary (2010)	PASS
Single coated plaster outer tape, tan nonwoven	3M Single Coated Medical Tape 9916 (Polyester) Manufacturer: 3M Medical Specialities	Product Clinical Data Summary (2010)	PASS

Part	Specification	Test report	Biokompatibilität
 <p>Disposable sensor</p>	Material: 3M Tape 1509 3M Tape 1525L 3M Tape 9916 Manufacturer: 3M Medical Specialities	Report: 3M Product Clinical Data Summary SDFY-2006-2027-2 SDFY-2006-2093-2	PASS

Following table includes materials of Disposable sensors with patient skin contact, related test reports including evaluations referred to biocompatibility.

Part	Specification	Test report	Biokompatibilität
 <p>Rubber sensor housing</p>	Material: Silikon Hersteller: Shenzhen YongCheng Silicone and Rubber Product Co., Ltd	Report: SDFY-2007-2509	PASS

Createdt: R. Dettweiler
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Approval:
Date:

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	Material: <i>Silikon</i> Hersteller: <i>Shenzhen YongCheng Silicone and Rubber Product Co., Ltd</i>	Report: <i>SDFY-2006-2027-1 SDFY-2006-2093-1</i>	PASS
Finger clip sensor pads			
	Material: <i>Silikon</i> Hersteller: <i>Shenzhen YongCheng Silicone and Rubber Product Co., Ltd</i>	Report: <i>SDFY-2006-2027-1 SDFY-2006-2093-1</i>	PASS
Wrap sensor housing			
	Material: <i>Silikon</i>	Report: <i>SDWH-2009-20900</i>	PASS
Ear sensor pads			
Raw cable of Finger clip sensor	Material: <i>PVC jacket 830-0082ENV Medical PVC 75 shore A</i>	Report: <i>SDFY-2006-2027-1 SDFY-2006-2093-1</i>	PASS
Raw cable of Rubber sensor, Wrap sensor	Material: <i>Silicone jacket 660.0123.05.00 S-EE-Flex</i>	Report: <i>SDFY-2008-2806</i>	PASS
	Material: <i>White and blue textiles</i>	Report: <i>SDWH-2009-21326</i>	PASS
Wrap sensor tape			