SUNRISE MEDICAL	1.1.k Biological evaluation and Material composition
Project Name:	StreetJet
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Biological assessment and selection of the scope of testing according to DIN EN ISO 10993-1: 2018 of components for use on manual and electric wheelchairs

Components with direct skin contact (Chapter 5.2)	Material	Contact duration (chapter 5.3)	cytotoxicity ISO 10993-5	sensitization ISO 10993-10	Irritation ISO 10993-11
Handlebar Grips	ISO1043-TPV-BLACK (RAL9005) 60-70 SHORE A	A-short-term <24h	X	(X)	(X)
Throttle Trigger	PA66-GF30; ABS	A-short-term <24h	X	(X)	(X)
Key technical features without direct skin contact	**Material**				
Toggle latch	zinc-plates steel with polyurethane red handle				
Clamp covers	PA 30%GF				
Main structural frame	304 Stainless Steel				
Drive wheel fork	A7020				
Central mounting plates	A6061				
Central mounting section external square tube	A6082				
Central mounting section internal square tube	304 Stainless Steel				
Height adjustment plates	304 Stainless Steel				
One touch clamp	6 grade Aluminium with 304 stainless steel handle				
Forward / Reverse Switch	PA66-GF30; ABS				
Locking Lever	Case-hardened Steel C10, zinc plated with plastic sleeve				
Display	PA66-GF30; ABS				
Battery	Plastic casing				
Stand	A7020				
Brake lever	Plastic				

The assessment of the biological test scope was carried out in accordance with EN ISO 10993-1: 2018. For the intended use of the components listed above, contact with intact skin is provided for a period of less than 24 hours. Therefore, a cytotoxicity test according to EN ISO 10993-5: 2009 is considered sufficient to assess the biocompatibility of the components listed in the table.

The gain in knowledge of further biocompatibility tests with these components contrasts with unnecessarily high damage of the experimental animals. In accordance with DIN EN ISO 10993-1: 2018 Chapter 4.6 and DIN EN ISO 10993-1 Chapter 6.2.1 b) 8), the performance of such tests is therefore waived.

We declare under our sole responsibility that the following product
StreetJet
Does not contain Latex in any componentry with direct skin contact in normal use

Date :	11/04/2022
Name / function:	Michael Sheen / RGK General Manager
Signature	

Attachment:

Tabelle A.1 — Bei der Beurteilung in Erwägung zu ziehende Prüfungen

Einteilung des Medizinproduktes nach			Biologischer Effekt							
Art des Körperkontaktes (siehe 5.2)		Kontaktdauer (siehe 5.3) A — kurzzeitig (≤ 24 h) B — länger (> 24 h bis 30 Tage) C — dauernd (> 30 Tage)	Zytotoxizität	Sensibilisierung	Irritation oder intrakutane Reaktivität	Systemische Toxizität (akut)	Subchronische Toxizität (subakute Toxizität)	Genotoxizität	Implantation	Hämokompatibilität
Kategorie	Kontakt									
Produkt mit Kontakt zu Körperoberflächen	Haut	A	X[a]	X	X					
		B	X	X	X					
		C	X	X	X					
	Schleimhaut	A	X	X	X					
		B	X	X	X					
		C	X	X	X		X	X		
	verletzte oder geschädigte Hautpartien	A	X	X	X					
		B	X	X	X					
		C	X	X	X		X	X		