

SILICONES FOR HEALTHCARE

Our solutions are **biocompatible** for long term application time **>30 days**. Zhermack silicones are tested to stay in contact with human body on **intact skin**.



**LONG TERM APPLICATION
>30 DAYS
INTACT SKIN**



Zhermack supplies room-temperature-curing **RTV-2 silicone rubber** grades which suit the **medical and biomedical industry** for several applications, such as:

- removable external prostheses
- silicone liners
- medical simulators
- anti-decubitus cushions
- therapeutic hosiery

WE SHAPE YOUR NEEDS

Zhermack 
Wellbeing

ZHERMACK BIOCOMPATIBLE PRODUCTS

BENEFITS

• High transparency	• Easily adaptable to skin temperature
• Biocompatibility	• Good resistance to a several number of solvents and chemicals
• Breathability	• No organic plasticizers involved
• No byproduct formation on curing	• Highly resistant to aging, weathering, heat and radiation
• Biodurability: low surface tension, thermal and chemical stability	

Study performed:

The following studies were conducted to determinate the biocompatibility of the product under examination according to iso 10993-1:

- **category: surface medical device**
- **contact: intact skin**
- **contact: duration long term (>30 d)**
- **category: surface medical device**
- **contact: mucosa**
- **contact: duration long term (<24 h)**

ENDPOINTS OF BIOLOGICAL EVALUATION	TEST GUIDELINE
CYTOTOXICITY	ISO 10993-5
SKIN SENSITIZATION	ISO 10993-10
SKIN IRRITATION	ISO 10993-23

Test material:

- ZA SFX 10 WT 10
- ZA SFX 0020

Manufacturer: Zhermack Spa, via Bovazecchino 100, 45021 Badia Polesine - Rovigo (Italy)

Results: the test item showed no relevant biological effects in the studies performed.

Study completion: August 2023.

Product	Colour	Hardness	WT (@23°C)	St (@23°C)	Tear Matric System (N/mm)	Tear B USA System (ppi)	Visc (cP)	Elongation at brack
ZA SFX 0020	traslucent	20 Sh00	25'	1h 10'	4	23	5.200	770%
ZA SFX 10 WT 10	traslucent	10 ShA	12'	40'	14	79	10.000	650%