

## BIOCOMPATIBILITY TESTS PERFORMED

### TESTED SAMPLES

RUTHINIUM DISC,  
RUTHINIUM DISC RX,  
RUTHINIUM DISC  
BICOLOUR, RUTHINIUM  
DISC NEUTRAL,  
RUTHINIUM DISC MULTILAYER,  
RUTHINIUM DISC MULTILAYER SC

### MANUFACTURER

DENTAL MANUFACTURING SPA  
RUTHINIUM GROUP  
VIA CA' MIGNOLA NUOVA, 1699  
BADIA POLESINE (RO) - ITALY

It is hereby declared that the medical devices listed above have been pool-tested for biocompatibility according to the international standard ISO 10993-1:2018, in detail:

- Chemical/physical characterisation test according to ISO 10993-18:2020/A1 2022
- Cytotoxicity test according to ISO 10993-5:2009 - **non-cytotoxic**
- In vitro skin irritation test according to ISO 10993-23:2021 - **non-irritant**
- GPMT Magnusson Kligman skin sensitisation test according to ISO 10993-10:2021 - **non-sensitising.**

Issue authorised by:

Bologna, 20/03/2023

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