



DECLARATION OF CONFORMITY

1. Reading Glasses
NREAD103
2. Name and address of the manufacturer:
Michael Pachleitner Group GmbH
Liebenauer Tangente 4
8041 Graz
Austria
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Objects of the declaration:
Models: NREAD103+1.50, NREAD103+2.00, NREAD103+2.50, NREAD103+3.00,
NREAD103+3.50
Brand: Visiosan

Details:
NREAD103+1.50 Frame-colour: black.
NREAD103+2.00 Frame-colour: black.
NREAD103+2.50 Frame-colour: black.
NREAD103+3.00 Frame-colour: black.
NREAD103+3.50 Frame-colour: black.
5. The objects of declaration described above are in conformity with the relevant Union 2007/47/EC (which amends the Medical Devices Directive MDD 93/42/EEC, the Active Implantable Medical Devices Directive AIMDD 90/385/EEC), Union regulation 2016/425/EU (PPE) and regulation 2001/95/EG.
6. References to the relevant harmonised standards used: EN standard 14139:2010, Anti-nickel regulation EN standard 12472:2005+A1:2009 + EN 16128:2015, EU regulation REACH 1907/2006.

Signed for and on behalf of: Michael Pachleitner Group GmbH, Liebenauer Tangente 4,
8041 Graz

Graz, 10th of January,
2019

Michael Rahm, CPO

Dietmar Hermus, CSO

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