

EU-Declaration of Conformity

We the

surgebright GmbH
Gewerbezeile 7, 4040 Lichtenberg - Austria
Phone: +(43) 720 371 355
SRN: AT-MF-000002664

declare on our own responsibility that the medical device

surgical instruments

with the intended use:

“Rotating, surgically invasive, reusable products for temporary use in the course of transplantation of Shark Screw® allografts”

Art. Nr.: see Table 1

Basis UDI-DI: 9120125220014E

class IIa

according to MDR 2017/745 Annex VIII, Rule 6,
meets all applicable requirements of the regulation (EU) 2017/745 (MDR)

The conformity assessment procedure according to Annex IX chapter 1,
is subject to the surveillance of the notified body:
mdc medical device certification GmbH (EU Identification Number: 0483)
Number of Certificate: D4008600003

26.02.2025, Lichtenberg
Date and place


Irene Rutzinger MSc, PRRC

Table 1: Product variants of the generic product group "surgical instruments"

Item number	Description
SCDR35	Shark Screw® drill, cannulated, Ø 2,85 mm
SCDR40	Shark Screw® drill, cannulated, Ø 3,25 mm
SCDR45L	Shark Screw® drill, cannulated, Ø 3,7 mm
SCDR50L	Shark Screw® drill, cannulated, Ø 4,2 mm
SCTA35	Shark Screw® tap, cannulated, Ø 3,5 mm
SCTA40	Shark Screw® tap, cannulated, Ø 4,0 mm
SCTA45L	Shark Screw® tap, cannulated, Ø 4,5 mm
SCTA50L	Shark Screw® tap, cannulated, Ø 5,0 mm