

## 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

***Insertion instruments***

with the intended use:

“Reusable surgical instruments for inserting human bone screws.”

Art. Nr.: see Table 1

Basis UDI-DI: 9120125220014E

class Ir

according to MDR 2017/745 Annex VIII, Rule 6, indent 2,  
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 " Insertion instruments"*

<b>Item number</b>	<b>Description</b>
C-08.00	Shark Screw® coupling
SCDRVacl	Shark Screw® driver acl
SCDRVcut	Shark Screw® driver cut
SCDRVh	Shark Screw® driver ht