

# EC Declaration of Conformity

We, the

**SanaPro Dental GmbH  
Stresemannstraße 46  
27570 Bremerhaven**

hereby declare under our sole responsibility that the medical device  
belonging to the UMDNS-group 17-619, restorative materials, dental, other,  
namely

## **BlancOne Seal, IDS-843**

is in compliance with the requirements  
of current version of the *Council Directive 93/42/EEC*.

### **Conformity Assessment**

*Procedure:*

According to Annex II excluding section 4 of the Council Directive 93/42/EEC.

*Classification:*

According to Annex IX Rule 8 of the Council Directive 93/42/EEC: Class IIa.

*Notified Body:*

Medcert Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH,  
Pilatuspool 2,  
20355 Hamburg,  
Identification-Number: 0482.

*Reference Standards:*

Applicable standards are part of the Technical Documentation. A list of the concerned standards can be looked up upon request.

Certificate No.:

7419GB410190708

*Validity:*

2023-12-09

Elmshorn, 2019-10-23

Place, date

  
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Dr. Marian Casny, Authorised Person