



# EC Design Examination Certificate

## Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

### pro med instruments GmbH

Bötzingen Straße 38  
79111 Freiburg  
Germany

that the design of the following device(s)

#### DORO® Blades

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.

This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 221096 MR2. Changes to the approved design are subject to further approval by the Notified Body.

**Basis of examination:** TF02\_A00\_Technische\_Doku\_DORO\_v1.4 dated 2015-04-15  
Produktakte PA 08-01 Mikrospatel und Spatel / DHF 15-005 dated 09.02.2018

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

**Examination report:** 411\_18d\_Bericht\_Produktprüfung\_DORO+Spatel\_V2 dated 2015-10-28  
411\_18d\_Bericht\_Produktprüfung-Hirnspatel-Pro Med-20180423 dated 2018-04-21

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	221096 MRA
Certificate unique ID	170712127
Effective date	2018-04-22
Expiry date	2020-10-27
Frankfurt am Main	2018-04-22

### DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.