EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Adoderm GmbH

Haslacher Weg 12b
51063 Köln
Germany

that the design of the following device(s)

Hyabell Lips, Hyabell Basic, Hyabell Deep, Hyabell Ultra, Hyabell Meso

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. 357444 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination:	"Hyabell-Lips", „Hyabell-Basic", „Hyabell-Deep", „Hyabell-Ultra" und „Hyabell-Meso" dated 2019-04-26 Datei: D.73.705-03 HYABELL (range) TECHNICAL FILE BD accessories 20-08-2020.pdf und Anlagen dated 2020-08-20 Further basis for the examination is referenced in the examination report and relating documents mentioned below.
Examination report:	19_Adoderm_EGA_Hyabell dated 2020-01-08 20_Adoderm_EGA_Hyabell_ÄM_08-2020_V2.docx dated 2020-09-07 The results of the examination are contained in the above mentioned report and the relating documents mentioned within.
Certificate registration no.	519869 MRA
Certificate unique ID	170771786
Effective date	2020-09-07
Expiry date	2024-05-26
Frankfurt am Main	2020-09-07

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.