



EC CERTIFICATE

Asskea GMBH

Haßlocher Str. 9
Gebesee 99189 GERMANY

Full Quality Assurance System Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Design and manufacture of medical suction equipment for use in aspiration and wound care

Device Classifications:

Class IIa

Device Descriptions and Model Type:

Please refer to Attachment: 1

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 1 attachment listing product references covered by this certificate.

File Number	A28346	Cycle Start Date	January 13, 2017
Certificate Number	773.180414	Effective Date	April 14, 2018
Initial Issue Date	January 13, 2014	Expiry Date	January 12, 2022

Authorised by

Paul Daysh

Medical Notified Body Operations Manager
For and on Behalf of UL International (UK) Ltd



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Status: [here](#)

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Attachment 1 of 1

The products detailed below are covered under the scope of this certificate:

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Medical Suction Equipment	M Serie Aspirators	M20	Class IIa	-
		M20D	Class IIa	-
		M30D	Class IIa	-
	S Serie Aspirators	S20	Class IIa	-
		S20K	Class IIa	-
		S30	Class IIa	-
	Mplus Serie Aspirators	M20Plus	Class IIa	-
		M30Plus	Class IIa	-
	proVisio	proVisio M28	Class IIa	-
		procuff-serie	procuff M	Class IIa
	prowound-serie	procuff S	Class IIa	-
		prowound M	Class IIa	-
	ped-serie	prowound S	Class IIa	-
		ped M	Class IIa	-
		ped S	Class IIa	-

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