

DECLARATION OF CONFORMITY

Revision: 3

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We

Name + address of manufacturer:	Microtek Medical B.V. Hekkehorst 24 7207 BN Zutphen / Netherlands
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declare on our own responsibility that

The medical device	Name Equipment Drapes
Type	Fluoroscope General Purpose Contamination Guards Camera Light Handle Covers X-Ray Controller Covers
Class according	Is Annex IX, rule 1

meets all the provisions of the Directive 93/42/EEC

Notified body	MEDCERT GmbH Pilatuspool 2 20355 Hamburg CE 0482	 Professional. Flexible. Medical Only.
Conformity assessment procedure	article 11 paragraph 2b 93/42/EEC acc. to Annex V	
Validity	15 May 2023	

Monheim am Rhein,
17.04.2018

Dieter Wirbals
Director
Regulatory Affairs EMEA

Place, date	Name and function
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DECLARATION OF CONFORMITY – PART LIST

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Medical Device	Device Subcategory	Part Number
Equipment Drapes	Fluoroscope	16630
		17626
		17629
		17630
		17631
		17632
		17647
		17656
		17657
		17660
		17668
		17669
		17675
		8080462
		4951UK
		4973UK
	General Purpose	17587
		17589
		17596
		17598
		17599
		17600
		17636
		17639
		17648
		3816UK
		3818UK
		3962UK
		4962UK
	Contamination Guards	17550
		47651
		17521

The PART LIST is updated and subject to revision control according to changes in the FORM "First of code CE list" (EURO F-003). Refer to the revision 5.

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Medical Device	Device Subcategory	Part Number
Equipment Drapes	Camera	2904UK
		4604UK
		5164UK
		5900UK
		9604UK
		9900UK
		9904UK
		17539
		17541
		17544
		18539
		18549
	Light Handle Covers	17557
		17558
	X-Ray	17610
		4954UK
	Controller Covers	17635
		17641
		17642

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