

# EC-Declaration of conformity

Supplier: AMNOTEC International Medical GmbH

Address: Take-off, Gewerbepark 9  
78579 Neuhausen ob Eck, Germany

Product: Reusable Surgical Instruments Class 1

	\$ number	UMDNS	UMDNS Discreption	GMDNS
	\$10-0010	12986	Percussors	11950
	\$10-0020	13750	Stethoscopes	37799
	\$10-0040	13043	Pinwheels	13043
	\$10-0100	15577	Dynamometers	15577
	\$10-0140	11893	Goniometers	11893
	\$10-0160	16417	Calipers, Other	39359
	\$10-0240	12293	Laryngoscopes	12293
	\$10-0260	12293	Laryngoscopes	12293
	\$10-0280	12235	Knife Handles	32365
	\$10-0600	15259	Trephines, Other	32574
	\$10-0640	15237	Probes, Other	32870
	\$10-0660	15689	Applicators, Other	10172
	\$10-0680	15868	Needle Guides	36129
	\$10-0700	15260	Trocars, Other	14154
	\$10-0740	11726	Fittings/Adapters	37428
	\$10-0840	15256	Syringes, Other	13929
	\$11-0020	15245	Scissors, Other	40251
	\$11-0200	15245	Scissors, Other	40251
	\$11-0220	13041	Cutters, Pin and Wire	40251
Product group	\$13-0020	14257	Tweezers	32377
	\$13-0040	14257	Tweezers	32377
	\$13-0060	14257	Tweezers	32377
	\$13-0100	14257	Tweezers	32377
	\$13-0120	14257	Tweezers	32377
	\$15-0040	15212	Clamps, Other	10861
	\$15-0140	10868	Clamps, Bulldog	10868
	\$15-0240	11791	Forceps, Sponge	11791
	\$15-0320	15212	Clamps, Other	10861
	\$15-0360	10894	Clip Appliers	32358
	\$16-0040	15242	Retractors, Other	32316
	\$16-0060	15249	Spatulas, Other	39379
	\$16-0180	15225	Hooks, Other	32356
	\$17-0020	15868	Needle Guides	36129
	\$17-0080	12726	Needle Holders	12726
	\$17-0200	15221	Forceps, Other	32377
\$20-0120	15226	Knives, Other	31899	
\$20-0220	15225	Hooks, Other	32356	
\$20-0260	11290	Dissectors	11290	
\$20-0280	15213	Clips, Other	38143	
\$20-0420	11958	Head Halter	11958	
\$20-0460	10678	Catheter Introducers	31745	

\$20-0700	15250	Spekula, other	
\$26-0040	11822	Gags	33453
\$26-0240	15225	Hooks, Other	32316
\$26-0580	14070	Tonsillectomes	14070
\$26-0640	11704	Filiforms	32589
\$26-0760	12549	Mirrors, Laryngeal	12549
\$26-0860	12293	Laryngoscopes	12293
\$26-0960	15245	Scissors, Other	40251
\$27-0120	13508	Scoops	32100
\$27-0280	14257	Tweezers	32377
\$27-0400	14255	Tuning Forks	14255
\$27-0420	13764	Stimulators, Auditory	13764
\$27-0440	15209	Catheters, Other	10685
\$27-0760	11702	Files, Bone	32378
\$27-0800	15237	Probes, Other	32870
\$27-0820	15234	Needles, Other	12729
\$28-0020	16667	Dental-Handinstruments, other	
\$31-0040	15254	Strippers, Other	13828
\$31-0140	16985	Tunnelers, Vascular	35950
\$33-0040	10156	Anoscopes	32063
\$33-0400	16264	Suture Units, Other	34600
\$33-0480	12335	Ligators, Hemorrhoid	32101
\$34-0400	17633	Urethrotomes	17633
\$34-0420	15215	Dilators, Other	11254
\$35-0280	16486	Depressors	16486
\$35-0560	15689	Applicators, Other	34157
\$35-0620	12990	Perforators, Amniotic Membrane	12990
\$36-0020	10678	Catheter Introducers	10678
\$36-0060	15560	Bougies	15560
\$40-0060	15244	Saws, Other	34821
\$40-0240	10825	Chisels, Bone	31906
\$40-0300	15240	Rasps, Other	32315
\$40-0420	13231	Punches, Bone	13231
\$40-0460	15243	Rongeurs, Other	31901
\$40-0480	15244	Saws, Other	34821
\$40-0580	15229	Mallets, Other	32312
\$40-1080	15224	Guides, Other	32311
\$40-1260	17760	Drill instruments	
\$40-1320	15224	Guides, Other	11925
\$40-1360	13041	Cutters, Pin and Wire	32886
\$43-0100	13517	Screwdrivers, Bone	13517
\$47-0120	13368	Retainers	37273
\$48-0020	13481	Scissors, Bandage	13481
\$48-0060	13708	Spreaders, Plaster	13708
\$48-0080	16341	Cast Cutters, Manual	16341
\$48-0100	12251	Knives, Plaster	35140
\$48-0120	16340	Cast Cutters, Electric	16340
\$49-0020	15239	Punches, Other	33967
\$49-0040	15245	Scissors, Other	40251
\$50-0240	11792	Forceps, Sterilizer Transfer	11792
\$51-0020	15561	Bowls	15561
\$51-0080	16767	Containers	16767
\$56-0160	15013	Cleaners	37412
\$40-0350	11084	Curette	32309
\$73-0080	15215	Dilator, other	37151
\$73-0100	15218	Elevator, other	13117
\$73-0120	10894	Clip applier	10894

\$74-0080	15221	Forceps, other	15628
\$74-0100	17574	Retrieval basket, biliary stone	15629
\$72-0020	10500	Brush	39284
\$71-0010	15748	Camera, endoscopy	32259
\$71-0020	18104	Adaptor, endoscope camera	36292
\$71-0030	12345	Light source, fiberoptic	42572
\$71-0050	11835	Trolley, medical devices	40596
\$73-0200	12750	Needle, pneumoperitoneal	12750

We declare on our own responsibility that the medical devices specified above, meets all the provisions of the Directive 93/42/EEC which apply for him.

This declaration concerns all denoted medical devices until the date 25.05.2020.

Conformity assessment procedure according Directive 93/42/EEC:

Document No	Title	Date of issue
93/42/EEC	Directive 93/42/EEC for Medical Devices Annex II <input type="checkbox"/> *, Annex V <input type="checkbox"/> *, Annex VII <input checked="" type="checkbox"/>	14/06/1993

**\*Notified Body:**

mdc medical device certification GmbH, Kriegerstrasse 6, 70191 Stuttgart

**Reg.-No:** 0483

Tuttlingen, 12.02.2019

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*(Handwritten Signature)*  
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