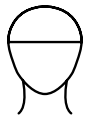


KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

DÉCLARATION DE CONFORMITÉ

DICHIARAZIONE DI CONFORMITÀ



PMS PRECISION MEDICAL SPECIALITIES GMBH

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1. EU-Konformitätserklärung / EU-Declaration of Conformity / EU-Déclaration de conformité / EU-Dichiarazione di conformità

Wir / We / Nous / Noi

PMS Präzisions Medizinische Spezialitäten GmbH
Kreuzstraße 5
78532 Tuttlingen
Germany

Single Registration Number (SRN) DE-MF-000009600

erklären hiermit in alleiniger Verantwortung, dass unsere Medizinprodukte

herewith declare on our own responsibility, that our Medical Devices

Déclarons sous notre propre responsabilité, que notre dispositif médical

Dichiariamo a nostra responsabilità, che i nostri dispositivi medici

Chirurgische Instrumente der Gruppe SPÜLEN-SAUGEN

die grundlegenden Sicherheits- und Leistungsanforderungen nach Anhang I der Verordnung (EU) 2017/745 erfüllen. Die Medizinprodukte unter Berücksichtigung der Verordnung (EU) 2017/745 (Kapitel II, Kapitel III, Kapitel V, Kapitel VI, Kapitel VII) gefertigt wurden und Konformitätsbewertungsverfahren unserer Produkte sowie die Zertifizierung unseres Managementsystems nach Anhang IX (ausgeschlossen Kapitel II) der Verordnung (EU) 2017/745 durchgeführt wurde von der

meet the essential safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 The medical devices have been manufactured in compliance with Regulation (EU) 2017/745 (Chapter II, Chapter III, Chapter V, Chapter VI, Chapter VII) and conformity assessment procedures of our products as well as the certification of our management system according to Annex IX (excluding Chapter II) of Regulation (EU) 2017/745 have been carried out by the

satisfont aux exigences essentielles de sécurité et de performance énoncées à l'annexe I du règlement (UE) 2017/745. Les dispositifs médicaux sont fabriqués en tenant compte ont été fabriqués conformément au règlement (UE) 2017/745 (chapitre II, chapitre III, chapitre V, chapitre VI, chapitre VII) et que des procédures d'évaluation de la conformité de nos produits et la certification de notre système de gestion conformément à l'annexe IX (à l'exception du chapitre II) du Règlement (UE) 2017/745 a été effectuée par la

soddisfano i requisiti essenziali di sicurezza e prestazione di cui all'allegato I del Regolamento (UE) 2017/745 I dispositivi medici sono stati fabbricati in conformità al Regolamento (UE) 2017/745 (Capo II, Capo III, Capo V, Capo VI, Capo VII) e le procedure di valutazione della conformità dei nostri prodotti e la certificazione del nostro sistema di gestione in conformità all'Allegato IX (escluso il capitolo II) del Regolamento (UE) 2017/745 sono state effettuate dal

Benannten Stelle

mdc medical device certification GmbH

Notified body

Kriegerstraße 6

Organisme notifié

70191 Stuttgart / Germany

Organo notificato

Nr. / No. 0483

Identifikationsnummer der Bescheinigung

D1470100006

Identification number of the certificate

Numéro d'identification du certificate

Numero di identificazione del certificato

Dokument	Version	Seite
TD03-1.04-DOCC-09-Konformitätserklärung	09	1 / 6

Gültig bis 27.02.2030

Valid until

Valable jusque

Valido fino a



Tuttlingen, 01.04.2026

Ort, Datum

Place, date

Lieu, date

Luogo, data

Herr Alexander Getz (Geschäftsführer / PRRC)

Name, Funktion und Unterschrift

name, function and sign

nome, fonction et signature

nome, finzione e firma

2. Zweckbestimmung

Artikelgruppe	Artikelbereich	Zweckbestimmung	Basis UDI-DI
Spülen und saugen	Alle Artikel	Chirurgische Augeninstrumente die benutzt werden, um während der Augenoperation zu spülen und saugen, die Iris einbeziehend.	42504166003JL

3. Artikelliste

Artikelnummer	Bezeichnung	Regel	Klasse	UMDNS Nummer	GTIN Nummer
E20-001	Bishop-Harmon AC Irrigator System	6	lr	10-573	04250416605733
E20-002	Silicone Bulb (autoclaveable)	6	lr	10-573	04250416605740
E20-003	Adaptor LL for silicone bulb	6	lr	11-729	04250416605757
E20-004	Bishop-Harmon Washout Cannula 19G	6	lr	10-573	04250416605764
E20-020SR	DSAEK AC Maintainer 20G	6	lr	10-573	04250416605849
E20-020ST	Lewicky AC Maintainer 20G	6	lr	10-573	04250416605856
E20-023PT	Heslin AC Maintainer Cannula polished	6	lr	10-573	04250416605917
E20-023TT	Heslin AC Maintainer Cannula textured	6	lr	10-573	04250416605924
E20-030	Rycroft Air Injection Cannula 30G	6	lr	10-573	04250416605948
E20-031	Rycroft Air Injection Cannula 27G	6	lr	10-573	04250416605955
E20-032	Rycroft Air Injection Cannula 25Gx5mm	6	lr	10-573	04250416605979
E20-033	Rainin Air Injection Cannula 30G flat	6	lr	10-573	04250416605986
E20-034	Rainin Air Injection Cannula 27G flat	6	lr	10-573	04250416605993
E20-043	McIntyre A.C. Cannula 30G straight	6	lr	10-573	04250416606044
E20-045	McIntyre A.C. Cannula 26G straight	6	lr	10-573	04250416606051
E20-046	McIntyre A.C. Cannula 23G straight	6	lr	10-573	04250416606068
E20-047	McIntyre A.C. Cannula 30G angled	6	lr	10-573	04250416606075
E20-048	McIntyre A.C. Cannula 26G angled	6	lr	10-573	04250416606082
E20-049	McIntyre A.C. Cannula 23G angled	6	lr	10-573	04250416606099
E20-055	Viscoelastic Irrigating Cannula angled	6	lr	10-573	04250416606105
E20-064	McIntyre-Binkhorst Cannula straight	6	lr	10-573	04250416606174

E20-065	McIntyre-Binkhorst Cannula left	6	lr	10-573	04250416606181
E20-066	McIntyre-Binkhorst Cannula right	6	lr	10-573	04250416606198
E20-089	Troutman Alpha-Chymotrypsin Cannula	6	lr	10-573	04250416606280
E20-141	Simcoe Capsule Polisher 23G/13mm curved	6	lr	10-573	04250416606471
E20-142	Simcoe Capsule Polisher 23G/21mm curved	6	lr	10-573	04250416606488
E20-145	Jensen PC Polisher 23G roughened tip	6	lr	10-573	04250416606518
E20-151	Simcoe Cortex Extractor 23G/13mm	6	lr	10-573	04250416606563
E20-152	Simcoe Cortex Extractor 23G/21mm	6	lr	10-573	04250416606570
E20-153	Charleux Cortex Extractor 23G/13mm	6	lr	10-573	04250416606587
E20-154	Charleux Cortex Extractor 23G/21mm	6	lr	10-573	04250416606617
E20-164	Gills Cortex Extractor 25G/5mm angled	6	lr	10-573	04250416606648
E20-167	Gills Cortex Extractor 25G/7mm angled	6	lr	10-573	04250416606655
E20-169	Gills Cortex Extractor 25G/9mm angled	6	lr	10-573	04250416606662
E20-201	Helsinki Hydrodissector 27G	6	lr	10-573	04250416606761
E20-203	Sautter Hydrodissector curved 27G	6	lr	10-573	04250416606785
E20-205	Pearce Hydrodissector 25Gx7mm angled	6	lr	10-573	04250416606808
E20-211	Kellan Hydrodissector 25G	6	lr	10-573	04250416606860
E20-213	Kellan Hydrodelineator 25G	6	lr	10-573	04250416606877
E20-231	Sheets Irrigating Vectis 23G serrated	6	lr	10-573	04250416606938
E20-300	Simcoe Original I/A Cannula	6	lr	10-573	04250416607003
E20-301	Simcoe Reverse I/A Cannula	6	lr	10-573	04250416607027
E20-400	Handle for coaxial I/A cannulas titanium	6	lr	10-573	04250416651655
E20-401	SL I/A Tip straight 0.35 mm port	6	lr	10-573	04250416659507
E20-404	SL I/A Tip curved	6	lr	10-573	04250416669032
E20-405	SL I/A Tip 45° angled	6	lr	10-573	04250416659514
E20-414	Silicone sleeve I/A Tip 21G/45° angled	6	lr	10-573	04250416651631
E20-415	Silicon Infusion Sleeve 21G (pack of 5)	6	lr	10-573	04250416651648
E20-420EF	EZFit Adaptor LL female-Luer male	6	lr	10-573	04250416607836
E20-421EF	EZFit Adaptor 2 x Luer male	6	lr	10-573	04250416607850
E20-422EF	EZFitAdaptor 2 x LL female	6	lr	10-573	04250416607874
E20-424	Vitreo Flushing Tube with metal adaptor	6	lr	10-573	04250416607881
E20-424T	Vitreo Flushing Tube titanium adaptor	6	lr	10-573	04250416607898
E20-425	Silicone Sleeve I/A Tip 23G/45° angled	6	lr	10-573	04250416651891
E20-426	Silicon Infusion Sleeve 23G (pack of 6)	6	lr	10-573	04250416651662
E20-426T	Vitreo Cleaning Adaptor titanium	6	lr	10-573	04250416607904
E20-427	Irrigation Handle 23G/0.6mm, smooth tip	6	lr	10-573	04250416651693
E20-428	Irrigating Handle 21G/0.8mm smooth tip	6	lr	10-573	04250416651709
E20-429	Irrigating Handle 20G/0.9mm, smooth tip	6	lr	10-573	04250416651716
E20-431EF	EZFit Bimanual Irrigation Cannula 21G	6	lr	10-573	04250416607928

E20-432EF	EZFit Aspiration Cannula 21G smooth	6	lr	10-573	04250416607935
E20-433EF	EZFit Aspiration Cannula 21G rough tip	6	lr	10-573	04250416607942
E20-434EF	EZFit Bimanual I/A System 21G smooth	6	lr	10-573	04250416607959
E20-435EF	EZFit Bimanual I/A System 21G rough	6	lr	10-573	04250416607966
E20-436	Aspirating Handle 23G/0.6mm rough tip	6	lr	10-573	04250416659521
E20-437	Aspirating Handle 22G/0.7mm rough tip	6	lr	10-573	04250416651884
E20-438	Aspirating Handle 21G, rough tip	6	lr	10-573	04250416651730
E20-439	Aspirating Handle 20G/0.9mm, smooth tip	6	lr	10-573	04250416651723
E20-440	Irrigation Handle titanium, male/female	6	lr	10-573	04250416607980
E20-441	EZFlo Irrigating Handle 21G smooth tip	6	lr	10-573	04250416607997
E20-442	EZFlo Irrigating Handpiece 21G rough tip	6	lr	10-573	04250416608000
E20-450	Aspiration Handle 2 x LM, titanium	6	lr	10-573	04250416608048
E20-451	Aspirating Handle 21G/0.3mm, smooth tip	6	lr	10-573	04250416608079
E20-452	Aspirating Handle 21G/0.3mm, rough tip	6	lr	10-573	04250416608086
E20-453	Aspirating Handle 21G/0.4mm, smooth tip	6	lr	10-573	04250416608093
E20-454	Aspirating Handle 21G/0.4mm, rough tip	6	lr	10-573	04250416608109
E20-480	Neuhann 20G rrigating Nucleus Rotator	6	lr	10-573	04250416651679
E20-481	DSAEK Endothelial Irrigating Stripper	6	lr	10-573	04250416608192
E20-482	Fine Irrigating Nucleus Chopper 20G	6	lr	10-573	04250416651686
E20-485	Rosen Irrigating Front Chopper 20G	6	lr	10-573	04250416608239
E20-486	Nagahara 60° Irrigating Front Chopper	6	lr	10-573	04250416608253
E20-487	Nagahara 2-Port Irrigating Chopper 20G	6	lr	10-573	04250416608277
E20-489	Nagahara 90° Irrigating Front Chopper	6	lr	10-573	04250416608291
E20-522	Vidaurri LASIK Cannula 25G horizontal	6	lr	10-573	04250416608413
E20-523	Buratto LASIK Cannula 23G flattened tip	6	lr	10-573	04250416608420
E20-525	Buratto LASIK Cannula 25G	6	lr	10-573	04250416608437
E20-526	Slade LASIK Cannula 26G	6	lr	10-573	04250416608444
E20-529	Banaji LASIK Cannula 25G	6	lr	10-573	04250416608468
E20-600	Galezowski 23G Lacrimal Cannula straight	6	lr	10-573	04250416608550
E20-601	Galezowski 23G Lacrimal Cannula curved	6	lr	10-573	04250416608567
E20-602	Shahinian 23G Lacrimal Cannula	6	lr	10-573	04250416608574
E20-612	Lacrimal Cannula 25G straight	6	lr	10-573	04250416608598
E20-612S	Lacrimal Cannula Silver straight	6	lr	10-573	04250416633668
E20-613	Lacrimal Cannula 25G short angled	6	lr	10-573	04250416608611
E20-613S	Lacrimal Cannula silver short angled	6	lr	10-573	04250416638632
E20-615	Larcimal Cannula 25G long angled	6	lr	10-573	04250416644749
E20-615S	Larcimal Cannula Silver 25G long angled	6	lr	10-573	04250416650504
E20-617	Lacrimal Cannula 25G large curve	6	lr	10-573	04250416638557



E20-617S	Lacrimal Cannula Silver large curve	6	lr	10-573	04250416638649
E20-622	Anel Lacrimal Cannula 23G straight	6	lr	10-573	04250416608673
E20-623	Anel Lacrimal Cannula 23G curved	6	lr	10-573	04250416608680
E20-630	Lacrimal Cannula 23G reinforced straight	6	lr	10-573	04250416608697
E20-631	Lacrimal Cannula 23G reinforced curved	6	lr	10-573	04250416608703
E20-642	West Lacrimal Cannula 23G side port	6	lr	10-573	04250416650665
E20-643	West Lacrimal Cannula 23G bottom port	6	lr	10-573	04250416651471
E20-645	West Lacrimal Cannula 23G front port	6	lr	10-573	04250416651488
E20-646	Bangerter Probe Cannula 23Gx40mm	6	lr	10-573	04250416608734
E20-647	Bangerter Probe Cannula 23G x 60 mm	6	lr	10-573	04250416648204
E20-672	Atkinson Peribulbar Needle 23G/22mm	6	lr	10-573	04250416639011
E20-673	Atkinson Retrobulbar Needle 23G/32mm	6	lr	10-573	04250416639035
E20-674	Atkinson Retrobulbar Needle 23G/38mm	6	lr	10-573	04250416639028
E20-683	Corbin Sub-Tenon Cannula 23G	6	lr	10-573	04250416608864
E20-685	Fukasaka Sub-Tenon Cannula 23G	6	lr	10-573	04250416608871
E20-687	Gross Sub-Tenon Cannula 21G	6	lr	10-573	04250416608888
E20-689	Stevens Sub-Tenon Cannula 21G	6	lr	10-573	04250416608895
E20-700	Blunt Tip Cannula 20G	6	lr	15-206	04250416608918
E20-700L	Blunt Tip Cannula 20G/LL	6	lr	15-206	04250416608925
E20-704	Tapered Tip Cannula 20/23G	6	lr	15-206	04250416608956
E20-704L	Tapered Tip Cannula LL 20/23G	6	lr	15-206	04250416608963
E20-723T	Cannula Inserter for 23G trocar system	6	lr	15-206	04250416609120
E20-730	Backflush Instrument passive aspiration	6	lr	15-206	04250416609144
E20-731	Backflush Handpiece passive aspiration	6	lr	15-206	04250416609151
E20-731LL	Backflush Handpiece with Luer-Lock	6	lr	15-206	04250416609168
E20-731LM	Backflush Handpiece with Luer male slip	6	lr	15-206	04250416609175
E20-731XL	Backflush Handpiece XL with LL adaptor	6	lr	15-206	04250416609199
E20-732	Silicone Reservoir passive aspiration	6	lr	15-206	04250416609212
E20-732XL	Silicone Reservoir extra large	6	lr	15-206	04250416609229
E20-740	Backflush Instrument active aspiration	6	lr	15-206	04250416609250
E20-741	Backflush Handle for active aspiration	6	lr	15-206	04250416609267
E20-741LL	Backflush Handle with Luer-Lock	6	lr	15-206	04250416609274
E20-741LM	Backflush Handle with Luer male adaptor	6	lr	15-206	04250416609281
E20-742	Silicone Reservoir for active aspiration	6	lr	15-206	04250416609298
E20-743	Silicone Tubing with LL cone for E20-741	6	lr	15-206	04250416609304
E20-752	Infusion Plug 20G x 2.5 mm beveled tip	6	lr	15-206	04250416609328
E20-754	Infusion Plug 20G x 4.0 mm beveled tip	6	lr	15-206	04250416609342
E20-756	Infusion Plug 20G x 6.0 mm beveled tip	6	lr	15-206	04250416609366
E20-805	All Glas Syringe with LL-cone, 5 ml	6	lr	13-929	04250416609472
E20-880	McIntyre Infusion Handpiece	6	lr	17-953	04250416609601



E20-881	McIntyre Aspiration Handpiece	6	lr	17-953	04250416609618
E20-882T	Irrigation Handle titanium	6	lr	17-953	04250416609632
E20-883T	Aspirating Handle titanium	6	lr	17-953	04250416609649