

**EG-KONFORMITÄTSERKLÄRUNG / EC DECLARATION OF CONFORMITY**

Henry Schein Inc.  
135 Duryea Road  
Melville, NY 11747  
USA

[EC|REP] Henry Schein Services GmbH  
Monzastraße 2 a  
D-63225 Langen  
Germany

Wir erklären in eigener Verantwortung, daß die sterilen Medizinprodukte mit den Anforderungen nach Anhang 1 der Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte übereinstimmen

*We hereby declare under our sole responsibility that the sterile medical devices are in compliance with Annex I of the Council Directive 93/42/EEC of 14. June 1993 concerning medical devices.*

Produktliste siehe Anhang 1

*Devices listed in Annex 1*

Konformitätsbewertungsverfahren nach Anhang V und VII der oben genannten Richtlinie.

*Conformity Assessment Procedure according to Annex V and VII of the Council Directive named above.*

Klassifizierung nach Anhang IX, (Regel 6) der oben genannten Richtlinie:

*Classification according to Annex IX, (rule 6) of the Council Directive named above:*

**Klasse I (Steril)**

*Class I (sterile)*

UMNDS-Nummer / UMNDS-Code  
16662 Dental Hand Instruments, Endodontic

Referenznormen:  
Anwendbare Normen sind Bestandteile der technischen Dokumentation und können auf Wunsch eingesehen werden.

*Reference Standards:  
Applicable Standards are part of the technical documentation which can be provided on request.*

Benannte Stelle / Notified Body:  
Medcert GmbH, Pilatuspool 2, D-20355 Hamburg - Identification No.: 0482  
Certification Number: 7425GB415200327 (Expiry date: 20.02.2024)

Gültig bis zum Ablauf des EG-Zertifikats

*Valid until expiry date of the EC certificate*

Signed for and on behalf of Henry Schein, Inc.:

**Henry Schein Inc.**  
135 Duryea Road  
Melville, NY 11747 USA

Guido Bloedorn  
Senior Director Quality & Regulatory Affairs EU

Friday, May 20, 2022

Date

**Anhang 1 / Annex 1**  
**Produktliste – Device List**

REF	Description
5701294	Maxima sterile hedstromfile 21 mm #10
5701296	Maxima sterile hedstromfile 21 mm #20
5701295	Maxima sterile hedstromfile 21 mm #15
5701297	Maxima sterile hedstromfile 21 mm #25
5701298	Maxima sterile hedstromfile 21 mm #30
5701299	Maxima sterile hedstromfile 21 mm #35
5701300	Maxima sterile hedstromfile 21 mm #40
5701301	Maxima sterile hedstromfile 21 mm #45
5701302	Maxima sterile hedstromfile 21 mm #50
5701303	Maxima sterile hedstromfile 21 mm #55
5701304	Maxima sterile hedstromfile 21 mm #60
5701271	Maxima sterile hedstromfile 21 mm #70
5701272	Maxima sterile hedstromfile 21 mm #8
5701273	Maxima sterile hedstromfile 21 mm Asst #15-40
5701274	Maxima sterile hedstromfile 25 mm #10
5701275	Maxima sterile hedstromfile 25 mm #100
5701276	Maxima sterile hedstromfile 25 mm #15
5701277	Maxima sterile hedstromfile 25 mm #20
5701278	Maxima sterile hedstromfile 25 mm #25
5701279	Maxima sterile hedstromfile 25 mm #30
5701280	Maxima sterile hedstromfile 25 mm #35
5701281	Maxima sterile hedstromfile 25 mm #40
5701282	Maxima sterile hedstromfile 25 mm #45
5701283	Maxima sterile hedstromfile 25 mm #50
5701284	Maxima sterile hedstromfile 25 mm #55
5701285	Maxima sterile hedstromfile 25 mm #60
5701286	Maxima sterile hedstromfile 25 mm #70
5701287	Maxima sterile hedstromfile 25 mm #8
5701288	Maxima sterile hedstromfile 25 mm #80
5701289	Maxima sterile hedstromfile 25 mm #90
5701290	Maxima sterile hedstromfile 25mm Asst #15-40
5701291	Maxima sterile hedstromfile 25mm Asst #45-80
5701292	Maxima sterile hedstromfile 31mm Asst 15-40
5701293	Maxima sterile hedstromfile 31mm Asst 45-80
5701260	Maxima sterile K File 21 mm #06
5701261	Maxima sterile K File 21 mm #08
5701262	Maxima sterile K File 21 mm #10
5701263	Maxima sterile K File 21 mm #100
5701264	Maxima sterile K File 21 mm #15
5701265	Maxima sterile K File 21 mm #20
5701266	Maxima sterile K File 21 mm #25
5701267	Maxima sterile K File 21 mm #30
5701268	Maxima sterile K File 21 mm #35
5701269	Maxima sterile K File 21 mm #40
5701270	Maxima sterile K File 21 mm #45
5701224	Maxima sterile K File 21 mm #50
5701225	Maxima sterile K File 21 mm #55
5701226	Maxima sterile K File 21 mm #60
5701227	Maxima sterile K File 21 mm #70
5701228	Maxima sterile K File 21 mm #80
5701229	Maxima sterile K File 21 mm #90
5701230	Maxima sterile K File 21 mm Asst #10-35
5701231	Maxima sterile K File 21 mm Asst #40-70
5701232	Maxima sterile K File 25 mm #06
5701233	Maxima sterile K File 25 mm #08
5701234	Maxima sterile K File 25 mm #10
5701242	Maxima sterile K File 25 mm #100
5701243	Maxima sterile K File 25 mm #10-35 Asst

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5701244	Maxima sterile K File 25 mm #15
5701245	Maxima sterile K File 25 mm #20
5701246	Maxima sterile K File 25 mm #25
5701247	Maxima sterile K File 25 mm #30
5701248	Maxima sterile K File 25 mm #35
5701249	Maxima sterile K File 25 mm #40
5701250	Maxima sterile K File 25 mm #40-70 Asst
5701251	Maxima sterile K File 25 mm #45
5701252	Maxima sterile K File 25 mm #50
5701253	Maxima sterile K File 25 mm #55
5701254	Maxima sterile K File 25 mm #60
5701255	Maxima sterile K File 25 mm #70
5701256	Maxima sterile K File 25 mm #80
5701257	Maxima sterile K File 25 mm #90
5701258	Maxima sterile K File 31mm Asst 10-35
5701259	Maxima sterile K File 31mm Asst 40-70
5701210	Maxima sterile Reamer 31 mm Asst # 10-35
5701211	Maxima sterile Reamer 31 mm Asst # 40-70
5701212	Maxima sterile Reamers 21mm #08
5701213	Maxima sterile Reamers 21mm #10
5701214	Maxima sterile Reamers 21mm #15
5701215	Maxima sterile Reamers 21mm #20
5701216	Maxima sterile Reamers 21mm #25
5701217	Maxima sterile Reamers 21mm #30
5701218	Maxima sterile Reamers 21mm #35
5701219	Maxima sterile Reamers 21mm #40
5701220	Maxima sterile Reamers 21mm #45
5701188	Maxima sterile Reamers 21mm #50
5701189	Maxima sterile Reamers 21mm #55
5701190	Maxima sterile Reamers 21mm #60
5701191	Maxima sterile Reamers 21mm #70
5701192	Maxima sterile Reamers 21mm #80
5701193	Maxima sterile Reamers 21mm Asst #10-35
5701194	Maxima sterile Reamers 21mm Asst #40-70
5701195	Maxima sterile Reamers 25 mm #08
5701196	Maxima sterile Reamers 25 mm #10
5701197	Maxima sterile Reamers 25 mm #100
5701198	Maxima sterile Reamers 25 mm #15
5701199	Maxima sterile Reamers 25 mm #20
5701200	Maxima sterile Reamers 25 mm #25
5701201	Maxima sterile Reamers 25 mm #30
5701202	Maxima sterile Reamers 25 mm #35
5701203	Maxima sterile Reamers 25 mm #40
5701204	Maxima sterile Reamers 25 mm #45
5701205	Maxima sterile Reamers 25 mm #50
5701206	Maxima sterile Reamers 25 mm #55
5701207	Maxima sterile Reamers 25 mm #60
5701208	Maxima sterile Reamers 25 mm #70
5701209	Maxima sterile Reamers 25 mm #80
5701185	Maxima sterile Reamers 25 mm #90
5701186	Maxima sterile Reamers 25 mm Asst #10-35
5701187	Maxima sterile Reamers 25 mm Asst #40-70
<i>End of list.</i>	

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