

# DECLARATION OF CONFORMITY



<b>Legal Manufacturer</b> <b>HENROTEK Aps, Vestermarksvej 5, 6630 Rødding, Denmark</b>	
This declaration of conformity is issued under the sole responsibility of the manufacturer and we hereby declare that the below mentioned products comply with the European Medical Device Regulation (EU) 2017/745 [MDR] and its relevant transposition into all national laws of the member states into which we place the device(s)	
SRN No.	DK-MF-000029313
Conformity Route:	MDR Annex II and Annex V
MDR Annex VIII Classification	Non-invasive, Class I (Rule 1)
Conformity with relevant regulations	European Medical Device Regulation (EU) 2017/745
Product Name and Description	HENRO-GRIP® cutlery for food only, PP (Polypropylene) TPE (Thermoplastic elastomer)  01) Right and left-handed spork up till 8 years 02) Right and left-handed spoon up till 8 years 03) Right and left-handed fork from 8 years 04) Right and left-handed spoon from 8 years 05) Right and left-handed knife from 8 years
Product REF #	1) Item No. 12792 Article No. 1520.100 Blue/white, right-handed  1) Item No. 12793 Article No. 1520.110 Green/white, left-handed  2) Item No. 12794 Article No. 1520.200 Blue/white, right-handed  2) Item No. 12795 Article No. 1520.210 Green/white, left-handed


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|  | <ul style="list-style-type: none"><li>3) Item No. 12801<br/>Article No. 1520.320 Grey/white, right-handed</li><br/><li>3) Item No. 12797<br/>Article No. 1520.340 Grey/white, left-handed</li><br/><li>3) Item No. 12807<br/>Article No. 1520.360 Red/white, right-handed</li><br/><li>3) Item No. 12809<br/>Article No. 1520.380 Red/white, left-handed</li><br/><li>4) Item No. 12798<br/>Article No. 1520.420 Grey/white, right-handed</li><br/><li>4) Item No. 12799<br/>Article No. 1520.440 Grey/white, left-handed</li><br/><li>4) Item No. 12808<br/>Article No. 1520.460 Red/white, right-handed</li><br/><li>4) Item No. 12810<br/>Article No. 1520.480 Red/white, left-handed</li><br/><li>5) Item No. 12796<br/>Article No. 1520.300 Grey/white, right and left-handed</li><br/><li>5) Item No. 12811<br/>Article No. 1520.400 Red/white, right and left-handed</li></ul> |
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Accessory Name and Description	HENRO-GRIP® Strap accessory for medical device HENRO-GRIP® cutlery
Accessory REF #	Item No. 12816 Article No. 1500.001 Dark grey utensil-holder
Basic UDI-DI (Global Model Number GMN)	57048313BY
Category of medical device:	Technical aids for disabled persons
Valid from date of delivery:	28.09.2023
Place and date of issue	Rødning - 28.09.2023
Signature	Mette Christensen Key Account Manager 

**HENROTEK®**

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CVR No.: DK 12482502