



EC-DECLARATION OF CONFORMITY

Legal Manufacturer

HENROTEK ApS
Vestermarksvej 5
DK-6630 Rødding
Denmark

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)

Conformity Route	MDR Annex II and Annex III
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® Grey Knife
REF #	AD160034
Purchase order no.	236100558
Basic UDI-DI (Global Model Number GMN)	57048313BY
Category of medical device	Technical aids for disabled persons
Valid from date of delivery	07-03-2023
Material descriptions	PP & TPE

Henrotek lot number	Quantity	Unit	Itemcode	Manufacture date
1251907	5	pieces	12796	01-02-2022

Place and date of issuer

Quality Lead

Rødding 07-03-2023



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Conformity Route	MDR Annex II and Annex III
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® Grey Spoon Right
REF #	AD155987
Purchase order no.	236100558
Basic UDI-DI (Global Model Number GMN)	57048313BY
Category of medical device	Technical aids for disabled persons
Valid from date of delivery	07-03-2023
Material descriptions	PP & TPE

Henrotek lot number	Quantity	Unit	Itemcode	Manufacture date
0924	5	pieces	12798	16-11-2022

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Conformity Route	MDR Annex II and Annex III
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® Green Spoon
REF #	AD127271
Purchase order no.	236100558
Basic UDI-DI (Global Model Number GMN)	57048313BY
Category of medical device	Technical aids for disabled persons
Valid from date of delivery	07-03-2023
Material descriptions	PP & TPE

Henrotek lot number	Quantity	Unit	Itemcode	Manufacture date
1193	10	pieces	12795	27-02-2023

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Conformity Route	MDR Annex II and Annex III
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 © Blue Spoon Right
REF #	AD127270
Purchase order no.	236100558
Basic UDI-DI (Global Model Number GMN)	57048313BY
Category of medical device	Technical aids for disabled persons
Valid from date of delivery	07-03-2023
Material descriptions	PP & TPE

Henrotek lot number	Quantity	Unit	Itemcode	Manufacture date
0923	10	pieces	12794	16-11-2022

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Conformity Route	MDR Annex II and Annex III
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 © Blue Spork Right
REF #	AD127268
Purchase order no.	236100558
Basic UDI-DI (Global Model Number GMN)	57048313BY
Category of medical device	Technical aids for disabled persons
Valid from date of delivery	07-03-2023
Material descriptions	PP & TPE

Henrotek lot number	Quantity	Unit	Itemcode	Manufacture date
0930	5	pieces	12792	18-11-2022

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Conformity Route	MDR Annex II and Annex III
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	Handycup® Blue
REF #	AD075870
Purchase order no.	236100558
Basic UDI-DI (Global Model Number GMN)	57048311BU
Category of medical device	Technical aids for disabled persons
Valid from date of delivery	07-03-2023
Material descriptions	Blue PolyCarbonate

Henrotek lot number	Quantity	Unit	Itemcode	Manufacture date
1198	50	pieces	13045	28-02-2023

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Conformity Route	MDR Annex II and Annex III
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	Handycup® Clear
REF #	AD075869
Purchase order no.	236100558
Basic UDI-DI (Global Model Number GMN)	57048311BU
Category of medical device	Technical aids for disabled persons
Valid from date of delivery	07-03-2023
Material descriptions	Clear PolyCarbonate

Henrotek lot number	Quantity	Unit	Itemcode	Manufacture date
1196	500	pieces	13033	28-02-2023

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Conformity Route	MDR Annex II and Annex III
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-Plate®
REF #	AD162323
Purchase order no.	236100558
Basic UDI-DI (Global Model Number GMN)	57048315C4
Category of medical device	Technical aids for disabled persons
Valid from date of delivery	07-03-2023
Material descriptions	PP

Henrotek lot number	Quantity	Unit	Itemcode	Manufacture date
0773	20	pieces	12813	06-10-2022

Place and date of issuer

Quality Lead

Rødding 07-03-2023

