

	K DESIGN S.R.L	23/10/2025
	DECLARATION OF CONFORMITY	Rev. 01
	BATHROOM STOOLS	Pag. 1 a 2

La Spezia, 23rd October 2025

DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 Of the European Parliament and The Council on Medical Devices (MDR)

It is stated that the below EU Declaration of Conformity is issued under the sole responsibility of:

Legal manufacturer:
K DESIGN SRL

with registered place of business in:
via Vincinella, Loc. Ghiarettolo,
19037 – Santo Stefano di Magra, (SP) Italy

SRN:

As a legal manufacturer **K DESIGN SRL** hereby declare under our sole responsibility, that the medical device listed below with related accessories conform with the relevant provision of Medical Devices regulation 2017/745. Each of the CE marked products listed below have been verified against defined criteria and found to be in compliance with the General Safety and Performance Requirements of Appendix I of the Medical Device Regulation 2017/745, prior to being placed on the market.

The product specified below is a “Technical aid for the disabled”, classified as Class I, medical device. The classification is based on the requirements of Annex VIII & Rule I, of the MDR. Conformity assessment was carried out according to Art. 52, pt. 7 after drawing up the Technical Documentation in accordance with Annex II and III. The CE mark has been affixed on the product according to Annex V of the MDR.

PRODUCT FAMILY: Bathroom Stools
BASIC UDI-DI: 803405510KDSTOOLSUV
GMDN: 34936 - Shower seat, non-powered
EMDN CODE: Y093303

PRODUCT LIST:

Product code	Description	UDI-DI/GTIN/EAN
EH-STA-PP-46	SQUARE STOOL HEIGHT ADJ. DMA KD	08034055100103
EH-STRA-PP-46	ROUND STOOL HEIGHT ADJ. DMA KD	08034055100110
EH-BSTA-PP-B-46	SQUARE STOOL HEIGHT ADJ. BLACK DMA KD	08034055100127
EH-BSTRA-PP-B-46	ROUND STOOL HEIGHT ADJ. BLACK DMA KD	08034055100134

EMDN CODE: Y093303

Ref. Declaration of Conformity file Bathroom Stools Rev 01 as of 10/2025



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Intended use:

The Bathroom stool range is designed to provide a comfortable and supportive seating options for various tasks in the bathroom. It is particularly useful for people who have difficult standing up for long periods of time, hence reducing their muscle fatigue or risk of injury due to slipping. It is important to ensure that the stool is set up on a firm, flat surface and adjusted to the correct height before use to ensure safety and comfort. The accessories further improve the comfortability of the user.

Year of first market distribution : 2016

Following harmonized norms and/or common specifications were used for conformity evaluation:
EN ISO 13485:2016+A11:2021, EN ISO 14971:2019+A11:2021, EN ISO 17966:2016, ISO 14001:2015.

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Roberto Buratta
Managing Director
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	BATHTUB SEATS	Pag. 1 a 2

La Spezia, 23rd October 2025

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PRODUCT FAMILY: Bathtub Seats
BASIC UDI-DI: 803405510KDBS6Th
GMDN: 34936 - Shower seat, non-powered
EMDN CODE: Y093303

PRODUCT LIST:

Product code	Description	UDI-DI/GTIN/EAN
EH-BSB-PP-46	BATHTUB SEAT WITH BACKREST DMA KD	08034055100097

EMDN CODE: Y093303

Intended use:

The Bathtub Seat is supposed to be used as a bench designed to avoid the use of the bottom of the bathtub, facilitating easy entrance and exit from it. The bathtub seat promotes the user independence during the bathtub stages of daily personal hygiene, offering an easier and safer way to take a bath. The accessories further improve the comfortability for the user.

Year of first market distribution : 2016

Following harmonized norms and/or common specifications were used for conformity evaluation:
 EN ISO 13485:2016+A11:2021, EN ISO 14971:2019+A11:2021, EN ISO 17966:2016, ISO 14001:2015.



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	BATHTUB SEATS	Pag. 2 a 2


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	K DESIGN S.R.L	23/10/2025
	DECLARATION OF CONFORMITY	Rev. 01
	COMMODE CHAIRS	Pag. 1 a 2

La Spezia, 23rd October 2025

DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 Of the European Parliament and The Council on Medical Devices (MDR)

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PRODUCT FAMILY: Commode Chairs (CMD)
BASIC UDI-DI: 803405510KDCMDZG
GMDN: 40539 – Commode, manual
EMDN CODE: Y093303

PRODUCT LIST:

Product code	Description	UDI-DI/GTIN/EAN
EH-BCMDA-46	COMMODE CHAIR W/ARMRESTS BLACK DMA KD	08034055100042
EH-BCMDBA-46	COMMODE CHAIR W/BACKREST & ARMRESTS BLACK DMA KD	08034055100059
EH-CMDA-00-46	COMMODE CHAIR W/ARMRESTS DMA KD	08034055100318
EH-CMDBA-00-46	COMMODE CHAIR W/BACKREST & ARMRESTS DMA KD	08034055100073

EMDN CODE: Y093303

Ref. Declaration of Conformity file Commode Chairs Rev 01 as of 10/2025



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EH-BC-46	BUCKET FOR COMMODOE CHAIR DMA KD	08034055100035
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EMDN CODE: Y091299

EH-CCMD4-00-46	SOFT CUSHION FOR COMMODOE CHAIR LIGHT GREY DMA KD	08034055100325
EH-CCMDH4-00-46	SOFT CUSHION FOR COMMODOE CHAIR W/HOLE LIGHT GREY DMA KD	08034055100066

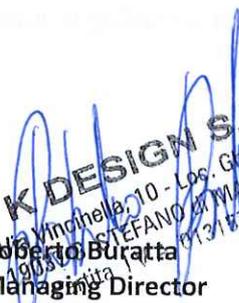
EMDN CODE: Y090699

Intended use:

The Commode Chair allows the user to achieve greater autonomy and independence while using the toilet and the shower by reducing muscle fatigue due to standing position as well as risk of injuries caused by slipping. The accessories, also used in the shower seats and chairs line, aim to further improve on the user's comfortability.

Year of first market distribution: 2022

Following harmonized norms and/or common specifications were used for conformity evaluation: EN ISO 13485:2016+A11:2021, EN ISO 14971:2019+A11:2021, EN ISO 17966:2016, EN ISO 14001:2015.


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	K DESIGN S.R.L	23/10/2025
	DECLARATION OF CONFORMITY	Rev. 01
	SHOWER SEATS AND SHOWER CHAIRS	Pag. 1 a 2

La Spezia, 23rd October 2025

DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 Of the European Parliament and The Council on Medical Devices (MDR)

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PRODUCT FAMILY: Shower Seats and Shower Chairs (SSSC)

BASIC UDI-DI: 803405510KDSSSC6X

GMDN: 34936 - Shower seat, non-powered

EMDN CODE: Y093303

PRODUCT LIST:

Product code	Description	UDI-DI/GTIN/EAN
Shower Seats		
EH-SS-PP-46	SHOWER SEAT DMA KD	08034055100233
EH-SSA-PP-B-46	SHOWER SEAT W/ARMRESTS DMA KD	08034055100240
EH-SSB-PP-B-46	SHOWER SEAT W/BACKREST DMA KD	08034055100257
EH-SSBA-PP-46	SHOWER SEAT W/BACKREST & ARMRESTS DMA KD	08034055100264
EH-BSS-PP-B-46	SHOWER SEAT BLACK DMA KD	08034055100271
EH-BSSA-PP-B-46	SHOWER SEAT W/ARMRESTS DMA KD	08034055100288
EH-BSSB-PP-B-46	SHOWER SEAT W/BACKREST DMA KD	08034055100295
EH-BSSBA-PP-B-46	SHOWER SEAT W/BACKREST & ARMRESTS BLACK DMA KD	08034055100301



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	K DESIGN S.R.L	23/10/2025
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Shower Chairs		
EH-SC-PP-46	SHOWER CHAIR DMA KD	08034055100158
EH-SCA-PP-46	SHOWER CHAIR W/ARMRESTS DMA KD	08034055100165
EH-SCB-PP-46	SHOWER CHAIR W/BACKREST DMA KD	08034055100172
EH-BSC-PP-46	SHOWER CHAIR BLACK DMA KD	08034055100196
EH-BSCA-PP-B-46	SHOWER CHAIR W/ARMRESTS BLACK DMA KD	08034055100202
EH-BSCB-PP-B-46	SHOWER CHAIR W/BACKREST BLACK DMA KD	08034055100219
EH-BSCBA-PP-B-46	SHOWER CHAIR W/BACKREST & ARMRESTS BLACK DMA KD	08034055100226
EH-SCBA-PP-46	SHOWER CHAIR W/BACKREST & ARMRESTS DMA KD	08034055100189

Intended use:

The Shower Seats & Shower Chairs line allows user to sit comfortably when taking a shower, reducing fatigue due to standing position as well as risk of injury due to slipping. The accessories, some of which are also used in commode chair line, aims to improve the user's comfortability.

Year of first market distribution : 2016

Following harmonized norms and/or common specifications were used for conformity evaluation:
EN ISO 13485:2016+A11:2021, EN ISO 14971:2019+A11:2021, EN ISO 17966:2016, EN ISO 14001:2015.


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	K DESIGN S.R.L	23/10/2025
	DECLARATION OF CONFORMITY	Rev. 01
	WALL MOUNTED SEATS	Pag. 1 a 2

La Spezia, 23rd October 2025

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PRODUCT FAMILY: WALL MOUNTED SEATS (PWS)

BASIC UDI-DI: 803405510KDPWS5G

GMDN: 34936 – Shower seat, non-powered

EMDN CODE: Y093303

PRODUCT LIST:

Product code	Description	UDI-DI/GTIN/EAN
PR-WSL-PP-46	WALL MOUNTED SHOWER SEAT W/LEGS DMA KD	08034055100349
PR-WA-PP-46	WALL MOUNTED ARMRESTS DMA KD	08034055100332
PR-WS-PP-B-46	WALL MOUNTED SHOWER SEAT DMA KD	08034055100004
PR-WSS-PP-46	WALL MOUNTED SHOWER SEAT SHORT DMA KD	08034055100356

EMDN CODE: Y093303

Ref. Declaration of Conformity file Wall Mounted Seats Rev 01 as of 10/2025



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	K DESIGN S.R.L	23/10/2025
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	WALL MOUNTED SEATS	Pag. 2 a 2

Intended use:

The Wall Mounted Seat is supposed to be used as a seat when showering hence reducing muscle fatigue due to standing position as well as injuries caused by slipping.

Year of first market distribution : 2015

Following harmonized norms and/or common specifications were used for conformity evaluation:
 EN ISO 13485:2016+A11:2021, EN ISO 14971:2019+A11:2021, EN ISO 17966:2016, EN ISO 14001:2015.

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