JYSK HANDI

hjælpemidler til børn og voksne siden 1990

DECLARATION OF CONFORMITY

CE

The undersigned, representing Jysk Handi, hereby declare that the following equipment is in accordance with: Directive 93/42 / EEC - 21.09.2007 - Medical equipment.

Manufacturer: **Jysk Handi**
Hornbjergvej 11
8543 Hornslet

Product: **Flexarm standard**

Model	**Vare nr.:**	**HMI nr.:**
with Ring and Spout Cup 500 mm	21 60 50	48 332
with Ring and Spout Cup600 mm	21 60 60	48 331
with Bottle Holder and Spout Cup 500 mm	21 60 51	48 330
with Bottle Holder and Spout Cup 600 mm	21 60 61	29 851

ISO Classification: 24 24 03 – 04

Classification: Medical Equipment Class I

Legislation: The equipment is CE marked and is in accordance with the essential requirements in Executive Order 1263 of 15 December 2008 on medical devices.

Standards: *Where applicable, the following standards and documents have been applied.*

DS/EN 12182:2012	Assistive products for persons with disability - General requirements and test methods
DS/EN 60601-1:2006	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
DS/EN 60601-1-11 :2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
DS/EN 60601-2-52:2010	Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds
DS/EN 50637:2017	Medical electrical equipment – Particular requirements for the basic safety and essential performance of medical beds for children
DS/EN 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
DS/EN 14971:2019	Medical devices – Application of risk management to medical devices
DS/EN 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
DS/ISO 7000:2019	Graphical symbols for use on equipment -- Registered symbols
DS/ISO 9999:2016	Assistive products for persons with disability – Classification and terminology

Comments: *Any significant requirements that are not completely met and why.*
None

TD 04.01 - Rev.02 / TD Rev.09EN

Date: October 2020

Rasmus Henriksen, Manager