COMED CERTIFIC CO 900 CERTIFIC CO 130 CERTIFIC COMED REF	Technical and Safety Specification Infusion foot with aluminium base 45 415 02 / 45 415 04 / 45 416 02 / 45 416 04 TCE1					Created on: 31.12.2008 Updated: 08.07.2016 Index: c Page 1/2	
 Device classification: Class 1 Duration: Temporary (rule 1) ANSM registration No: FR/CA01/0004344V 				Applied rule (annex IX) Non-Invasive (regulation 5 # 1) Non active therapeutical device Non surgical Non active medical device Non active device for diagnosis 			
General description		infusion l				ooks) and 5-footed base, the height of the device	
Attachments	Yes		+ user instructi	ions + pa	arts list		
Batch reference	No			- 194			
Connected device	No						
Single use device	No						
Sterile device	No						
Sterilisation	No						
Autoclavable	No						
Cleaning	Yes	With a product that does not attack stainless steel, aluminium or plastic in					
Unsuitable substance	Products that attack stainless steel, polyamide, and nylon						
Component parts		 level, dimensions 1000mm x Ø30mm x 1.2mm. Identical telescopic rod measuring 1200mm x Ø16mm x 1mm. Base: 5 feet in aluminium with polyamide caster wheels, 2 with clamps. Bottle holder: 2 or 4 nylon or stainless steel hooks. 					
Material	Stainless ste	el rod, alı	uminium base, I	nylon or	stainless steel hooks		
Contains latex	No						
Labelling	Yes	CE/MOD/NAME thermal printed at the top of the supporting rod					
Packaging	Yes	Cardboard with plastic sleeve for the rods					
Special packaging	No						
Marking on medical device	No	02	45 415 0	4	4E 44(02	4E 414 04	
References Designation	45 415 2 plastic		4 plastic ho		45 416 02 2 stainless steel hooks	45 416 04 4 stainless steel hooks	
Dimensions (cm)		I		Appe	ndix 1	·	
Net weight	305	0	3060		3050	3150	
Temperature resistance (C°)	Max = + 40, Min = -5						
Load weight (kg)			Ma	aximum:	2 per hook		
Usage			ags or pouches.	•	•		
Instruction for use	Attach the infusion bottles or pouches to the hooks and adjust to the desired height using the telescopic rod, then tighten using the knob. If necessary, lock the stand in place by applying the wheel clamps (2).						
Precautions for use	The hooks can hold a maximum weight of 2kg. The maximum height is 2100mm. Ensure the floor surface is flat or at a gradient of less than 5.7° (10%) in order to prevent toppling. Never lift with pouches attached. Always extend the base by using the rod, holding it 25mm from the locking screw.						
Recycling/Recovery	No/In metal waste containers.						
WEEE/REACH	No/No						
Safety data	R-Phrases = None Combination phrases = None						
Applicable standards	NF EN ISO 9001 : 2015 ; NF EN ISO 13485 : 2012 NF EN 1041 : 2008 + A1 : 2013 NF EN ISO 14971 : 2013 NF EN ISO 15223-1 : 2012 NF ISO 15223-2 : 2010						

Editor: Marion KLEIN Role: QA Initials: MK	COMED sas 8 rue Louise Michel 67200 STRASBOURG - France <u>www.comed.fr</u>

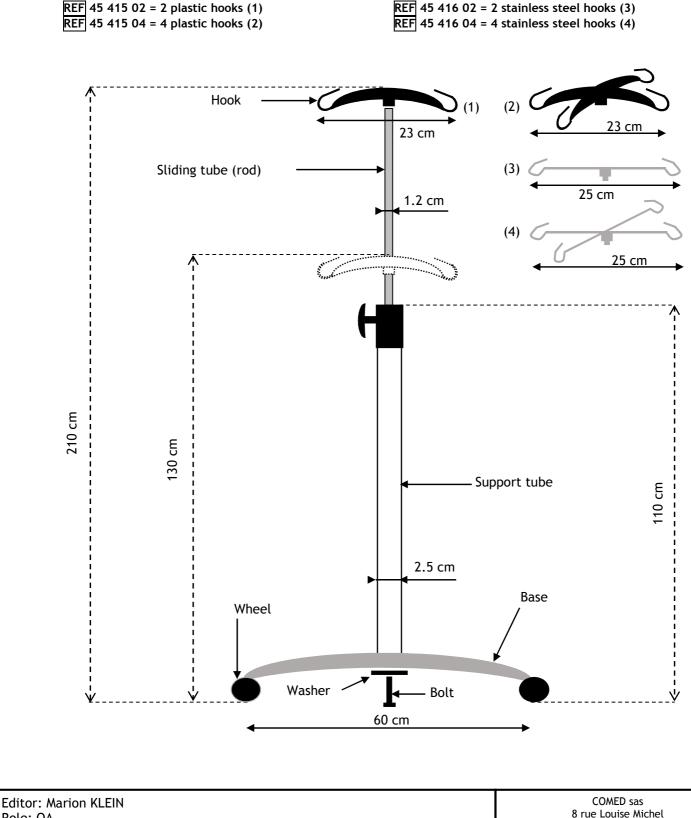


Page 2/2

TCE1

ANNEX 1:

To assemble, insert the rod with the black tip into the 5-footed base and fix in place using the bolt, placing the washer underneath the frame. Clean the two rods with a cleaning product before using for the first time. 2 lockable wheels are provided.



Role: QA Initials: MK COMED sas 8 rue Louise Michel 67200 STRASBOURG - France www.comed.fr