Part Numbers and Descriptions

Part Number	Description	Extended Description	GTIN	Model
0310300	Radiant Warmer Ceratherm 600-3 without mounting bracket	Ceramic 600W heating element with fast warm-up. Four programmable warming settings. LED light with 2 levels of illumination.	5051826024096	521A-60020-3-EX
0310301	Radiant Warmer Ceratherm 600-3 with fixed wall mounting bracket	Ceramic 600W heating element with fast warm-up. Four programmable warming settings. LED light with 2 levels of illumination. Fixed height mounting bracket, extendable from 255mm to 380mm in 25mm increments.	5051826011133	521A-60023-3-EX
0310302	Radiant Warmer Ceratherm 600-3 with double hinged arm and wall mounting bracket	Ceramic 600W heating element with fast warm-up. Four programmable warming settings. LED light with 2 levels of illumination. Double hinged fixed-height mounting arm allows the warmer to fold away flat to the wall when not in use.	5051826011140	521A-60022-3-EX
0310303	Radiant Warmer Ceratherm 600-3 with double jointed arm and ceiling anchorage with height adjustment (spring loaded arm)	Ceramic 600W heating element with fast warm-up. Four programmable warming settings. LED light with 2 levels of illumination. Ceiling mounted arm allows height adjustment.	5051826011157	521A-60024-3-EX
0310304	Radiant Warmer Ceratherm 600-3 on mobile floor stand with height adjustment	Ceramic 600W heating element with fast warm-up. Four programmable warming settings. LED light with 2 levels of illumination. Mobile floor stand has 3 lockable castors and height adjustment.	5051826011164	521A-60035-3-EX
0310305	Radiant Warmer Ceratherm 600-3 with double jointed arm and wall mounting bracket with height adjustment (spring balanced arm)	Ceramic 600W heating element with fast warm-up. Four programmable warming settings. LED light with 2 levels of illumination. Double jointed arm allows height adjustment.	5051826024102	521A-60025-3-EX
0310311	Fixed wall mounting bracket	for use with 0310301	5051826048443	521-071204-EX
0310312	Double jointed arm and wall mounting bracket	for use with 0310302	5051826048450	521-093008300-EX
0310313	Double jointed arm and ceiling anchorage, with height adjustment (spring loaded arm)	for use with 0310303	5051826048467	523A-24-3-EX
0310314	Mobile floor stand, with height adjustment	for use with 0310304	5051826048474	523-90057150-EX
0310315	Double jointed arm and wall mounting bracket, with height adjustment (spring balance arm)	for use with 0310305	5051826048481	523A-25-3-EX

MEDICAL DEVICE PAQ 2018 (MASTER BLANK TEMPLATE)

Key	
	Requires mandatory text input
	Requires conditional YES/NO input (or for EITHER/OR responses to be selected)
	Requires mandatory YES input
	Requires conditional text input (eg "if YES...")

PART I - PRODUCT INFORMATION

to be completed by the device Manufacturer or Authorised Representative

PRODUCT DETAILS:

UDI Device Identifier: (GS1-GTIN)		Covers multiple models, see attached appendix
Device Description:		Ceratherm 600-3 Radiant Warmer
(GMDN Code / Group if available)		
Type:	Make:	Nufer Medical AG
	Model:	Ceratherm 600-3
Manufacturer:		Nufer Medical AG
Supplier:		Viamed Ltd.
EU Authorised Representative:		Nufer Medical AG

1 a) When was this Model first placed upon the market ?
b) Is this Model still in production ?
c) Does this Form cover a range of Model variants ?
d) Does this Form cover Accessories ?
e) Has a Device brochure and specification been attached to this Form ?

REGULATORY COMPLIANCE:

2 a) Is the Device CE-marked, for its intended use, to all currently applicable EC Directives ?
b) - if YES, have the EC Declaration/s of Conformity been attached to this Form ?
c) Which EC Directive/s apply ?
Medical Devices Directive
Active Implantable Devices Directive
In-Vitro Diagnostics Medical Device Directive
Other/s
- which Directive/s?
c) Has this included Notified Body conformity assessment ?
- Notified Body identification number & name:
d) Is the manufacturer currently certified to any management / quality system Standards ?
- which Standard/s ?
- Certification Body:

3 If not CE-marked, (or if 'off-label' use is proposed for a CE-marked Device), then -
a) Is this a Medical Device for 'Clinical Investigation' ?
- if YES, quote the MHRA 'no objection' reference number:
- if YES, has a copy of the MHRA's notice of 'no objection' been attached to this Form ?
b) Is this an In-Vitro Diagnostic Medical Device for 'Performance Evaluation' ?
- if YES, has a copy of notification to MHRA been attached ?

c) Is this a 'custom-made' Medical Device ?
- if YES, name the prescribing Medical Practitioner:
d) - if NO to 2(a), and to 3(a) (b) and (c), then provide justification of the Device's status (e.g.: MHRA-approved humanitarian grounds)-

PRODUCT COMMITMENT:

4 a) To what date is manufacturer support for this Model guaranteed ?
- does this include availability of parts and supply of consumables / accessories ?
- does this include product support, as detailed below, (training, maintenance, repair, etc.) ?
b) What is the Device warranty period?
c) What is the recommended working lifetime for this Device?
d) Have details for end-of-life waste management of the Device been attached to this Form ?
e) Does the manufacturer / supplier have a robust system for notification of Device alerts / upgrades to a named hospital representative ?

PRODUCT SUPPORT:

5 a) Can an additional User Manual be provided (electronic format) ?
b) Can a Technical Manual be provided (electronic format) ?
c) Is identical loan equipment normally available in the event of equipment failure ?
(Any conditions or costs associated with 5(b) or 5(c) should be included in the response to 7(b))

Commissioning & Deployment

6 a) Has a protocol for post-delivery inspection and acceptance testing of Device function and safety been attached to this Form ?
b) Does the Device have particular installation requirements and / or require ancillary services or other prerequisite arrangements ?
- if YES, then have details of all installation requirements been attached to this Form ?

Technical Support

7 a) Is this a disposable non-serviceable device ? (- if YES, proceed to Section 8)

b) Does the manufacturer or an authorised servicing agent provide a maintenance / repair and technical support service ?
- if YES, then have details of all service contract options been detailed, fully costed and attached to this Form ?
- where is the servicing facility located ?
- are all servicing staff verifiably trained and competency assessed for the servicing tasks that they perform ?
- are qualification / competency records of servicing staff available upon request ?

c) Is the servicing organisation currently certified to any management system Standards ?
- which Standard/s ?
- Certification Body:

d) Do the contract alternatives offered in 7(b) include an option for in-house equipment servicing by hospital staff ?
- if YES, have details of the availability of spare / replacement parts to support equipment servicing been attached to this Form ?
- if YES, have details of information / test equipment / tooling / software required for equipment servicing been attached to this Form ?

Decontamination

8 a) What level of Device decontamination is required ? - (for multi-component systems identify all applicable levels)
- if answer is not 'none', have validated decontamination instructions been attached to this Form?
- for sterilisable Devices, do these instructions meet the requirements of EN-ISO-17664 ?

b) Does the device require processing / reprocessing before / between uses ?
- if YES, have all decontamination process requirements for special equipment, tools and materials been detailed in attached information ?
- if YES, have any special post-processing Device storage requirements been detailed in the attached information ?
- is there a limit to the number of Device reprocessing cycles ?
- are Devices uniquely identifiable ?
- is this an implantable Device ?

Data Security

9 a) Does the Device store or transmit patient information that will require information governance measures ?
- if YES, then have details of information capture / encryption / storage / transmission / deletion been attached to this Form ?

b) Does the Device interface, by wired or wireless connection, with Information technology (IT) equipment or network systems ?
- if YES, then have details of Device IT software / hardware compatibility requirements been attached to this Form ?
- if YES, then have details of provisions made for Device IT cybersecurity been attached to this Form ?

Particular Requirements

10 a) Does the Device present particular hazards that require special safety management measures ?
(eg: ionising / non-ionising radiation; contamination / infection; hazardous materials; hazardous mechanical / electrical energy; etc.)
- identified hazards:
- if YES, then have details of the nature of identified hazards been attached to this Form ?

b) Does the Device require particular performance quality assurance measures ? (eg: calibration, qualification, PoCT controls, etc.)
- QA measures:
- if YES, then have details of quality assurance requirements been attached to this Form ?

IMPLEMENTATION SUPPORT:

11 a) Is competency-based user training available from the manufacturer or an authorised provider ?
- if YES, have details of user training offered (amount / content / assessment / duration / location / cost / etc.) been attached ?

b) Is competency-based technical (equipment servicing) training available from the manufacturer or an authorised provider ?
- if YES, have details of technical training offered (amount / content / assessment / duration / location / cost / etc.) been attached ?

c) Is competency-based decontamination / reprocessing training available from the manufacturer or an authorised provider ?
- if YES, have details of decontamination training offered (amount / content / assessment / duration / location / cost / etc.) been attached ?

d) Are qualification / competency records of training providers available upon request ?

e) If other additional support facilities are available, (eg: helpdesk, literature, website resources, etc.), have details of these been attached ?

DECLARATION:

Please ensure that all necessary supplementary information, (as indicated by shaded boxes in the Form above) accompanies this Form.

1.c) List of all Model variants covered by this Form
1.d) List of all Accessories covered by this Form
1.e) Device brochure / specification
2.b) EC Declaration/s of Conformity
3.a) MHRA's notice of 'no objection' for Medical Device 'Clinical Investigation'
3.b) Notification to MHRA for In-Vitro Diagnostic Medical Device 'Performance Evaluation'
4.b) Warranty details
4.d) Details for end-of-life waste management of the Device
6.a) Protocol for post-delivery Device inspection / acceptance testing
6.b) Details of installation requirements
7.b) Service support contract options for maintenance / repair
7.d) Availability of spare / replacement parts
Information / test equipment / tooling / software required for Device servicing
8.a) Validated decontamination instructions / protocols
8.b) Requirements for special reprocessing equipment, tools and materials
Details of special post-processing Device storage requirements
9.a) Details of patient information capture / encryption / storage / transmission / deletion
9.b) Details of Device IT software / hardware compatibility requirements
Details of provisions made for Device IT cybersecurity
10.a) Details of particular hazards that require special safety management
10.b) Details of particular performance quality assurance measures required
11.a) Details of user training offered
11.b) Details of technical training offered
11.c) Details of decontamination training offered
11.e) Details of any additional support facilities offered

We agree that the NHS organisation will be entitled to rely upon the contents of this Form and its attachments, and that subsequent non-compliance with the statements contained herein will

Name:	Steve Hardaker
Position:	Technical Support Manager
Company:	Viamed Ltd.
Address:	15 Station Road, Cross Hills, Keighley, BD20 7DT
Website:	www.viamed.co.uk
Email:	info@viamed.co.uk
Signature:	SJH
Telephone:	01535 634542
Date:	16/06/20

PAQ Form (Part-I) – Declaration Reference No.: 03103xx-2018

PART II – TRANSACTION DETAILS

for completion by the device Supplier (eg: Manufacturer, Authorised Representative or other)

Previous sections in PART I provided general product information; this PART II addendum provides details specific to particular transaction/s for supply of the product:-

PRODUCT INFORMATION:

This statement is to be read in conjunction with product information provided in PAQ FORM (Part-I) Declaration Reference No.:
Dated:

TRANSACTIONAL:

14 a)	On what basis will the product be supplied, (including Devices for clinical investigation / research) ?
b)	For supply by loan or donation, other than Devices for clinical investigation / research - Is the Supplier on the Department of Health & Social Care (DHSC) Master Indemnity Agreement (MIA) Register ? (Note: unregistered Suppliers are advised to register for the MIA Overarching Agreement with the DHSC) - if YES, has a Department of Health & Social Care (DHSC) MIA Call-Off Agreement Form been attached ? DHSC MIA registration number: - if NO, has an Indemnity Insurance Certificate (for local indemnity agreement with the customer) been attached ?
c)	For supply by loan or donation of Devices for clinical investigation / research - Has confirmation of Health Research Authority (HRA) approval, including indemnity arrangements, been attached ?
d)	Is the particular item to be supplied a pre-used product ? - if YES, has usage and full service history been attached to this Form ?
15 a)	Are there any outstanding Field Safety Corrective Actions / Field Safety Notices relating to this product? - if YES, are issued Notices / Alerts attached to this Form ?

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Telephone:	01535 634542
Date:	16/06/20

			2012
	YES	if NO, when did production cease ?	
	YES	if YES, list of Models attached to this Form ?	YES
	YES	if YES, list of Accessories attached to this Form ?	YES
	YES		

	YES			
	YES			
	YES	Classification?	IIb	<(Enter: 1, 1-m, 1-s / IIa / IIb / III)
NO				
NO		Category?		<(Enter: general / self-test / List-A / List-B)
NO				
	YES			
TUV 0123				
	YES			
ISO 13485:2016		<(eg: EN-ISO-9001, 13485, 14001, etc.)		
TUV				

NO	YES		
	YES		
NO	YES		
	YES		

NO	YES		

2027-06			
YES			
YES			
12 months		Have warranty details been attached to this Form ? >	YES
Not specified by manufacturer		<('not applicable' for disposable Devices)	
YES			
YES			

	YES
	YES
NO	

	YES
NO	
	YES

NO		
	YES	
	YES	
Cross Hills, Keighley		
	YES	
	YES	
	YES	
ISO 13485:2016		<(eg: EN-ISO-9001, 13485, 17025, etc.)
BSI		
	YES	
	YES	
	YES	

	cleaning	disinfection
	YES	
	YES	
NO		
	YES	
	YES	
NO		
	YES	
NO		

if YES, what is the limit ? <(state if 'Single-Use')

NO	
	YES
NO	
	YES
	YES

	YES
Possible risk of burns to patient and/or operator	
	YES
NO	
	YES

NO	
	YES
NO	
	YES
NO	
	YES
	YES
	YES

ATTACHED	
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entitle the NHS organisation to seek redress.

03103xx-2018
16/06/20

purchase ?				

NO YES

YES

YES

YES

NO

YES

NO YES

YES