



## **EC DECLARATION OF CONFORMITY**

Following the provisions of the medical devices directive 93/42/EEC Annex II, without Section 4 and of the ROHS directive 2011/65/EU

We

**Manufacturer**

Datex-Ohmeda, Inc.  
9900 Innovation Drive  
Wauwatosa, WI 53226  
USA

**EU Authorized Representative**

GE MEDICAL SYSTEMS SCS  
283 Rue De La Minière  
78530 Buc, France

**Manufacturing Site**

Datex-Ohmeda, Inc.  
3030 Ohmeda Drive  
PO Box 7550  
Madison WI 53707-7550 USA

Declare under our sole responsibility that the class IIb device:


Panda iRes Warmer M1112198  
GMDN Code: 17433 (Warmer, radiant, infant)  
Classification rule (93/42/EEC Annex IX) : 9 Class IIb

To which this declaration relates is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it. In addition, the product is in conformity with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (as assessed by the manufacturer).

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical File Ref.: DOC2040067, of the product to which this declaration relates.
  - EC certificate: approval of full quality assurance system (Annex II of the medical devices directive 93/42/EEC delivered by TUV Rheinland LGA Products GmbH (Notified Body N° CE 0197 on 27/Feb/2020 / Certificate N° CE HD 60145555 0001).
  - List of harmonized standards applied for CE marking is included in the Technical File
- For the directive 2011/65/EU (RoHS)
  - Technical Documentation File DOC2040067, of the product to which this declaration relates

Authorized Signature:

  
Agata Anthony  
Regulatory Affairs Executive

  
Date

This EC declaration of conformity supersedes the previous declaration dated 13-August -2020.

DOC2050130



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PO Box 7550  
Madison WI 53707-7550 USA

Declare under our sole responsibility that the class IIb device:


Giraffe Warmer M1118179  
GMDN Code: 17433 (Warmer, radiant, infant)  
Classification rule (93/42/EEC Annex IX) : 9 Class IIb

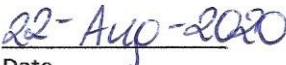
To which this declaration relates is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it. In addition, the product is in conformity with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (as assessed by the manufacturer).

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PO Box 7550  
Madison WI 53707-7550 USA

Declare under our sole responsibility that the class IIb device:

Panda Freestanding Warmer 2063568-001


GMDN Code: 17433 (Warmer, radiant, infant)  
Classification rule (93/42/EEC Annex IX) : 9 Class IIb

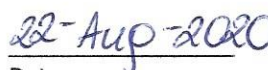
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Declare under our sole responsibility that the class IIb device:

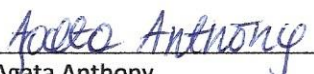
Panda Wall Mount Warmer      2063570-001  
GMDN Code: 17433 (Warmer, radiant, infant)  
Classification rule (93/42/EEC Annex IX) :9 Class IIb

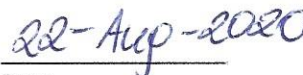
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