

# **"EC" DECLARATION OF CONFORMITY**

## **Bergeron Health Care**

*(Manufacturer)*

**15 South Second Street, Dolgeville, New York 13329, USA**

*declare on our own responsibility that product*

Brand: Special Tomato  
Product Name: Soft-Touch® Sitter  
Risk Class: Class I  
SRN: DK-AR-000007351  
UDI: See Attachment  
EU Rep: Global Carehab

*complies with the assessment criteria of Council's Directives:*

**Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017**

*and the quality system of the manufacturer is in conformity with Good Manufacturing Practices as detailed by: US Food & Drug Administration, Code of Federal Regulations, Title 21, Volume 8ref CITE: 21CFR820.50*



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Steve Fischer, Vice President

June 30, 2021

Date