

"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 with Floor Base
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



Steve Fischer, Vice President

June 30, 2021

Date