

EC DECLARATION OF CONFORMITY

Bergeron Health Care

declare on our own responsibility that product

Brand:	Special Tomato
Product Name:	Sitter
Intended Purpose:	The Special Tomato Soft-Touch® Sitters encourage well being through properly designed clinically correct seating support for children with mild to moderate seating deficiencies. It is available for purchase with a static floor base, a wooden mobile base with casters, and as a standalone product.
Manufacturer:	Flocast dba Bergeron Health Care 15 South Second Street Dolgeville, NY 13329 USA
Risk Class:	Class I, per EU Medical Device Regulation 2017/745 Annex VIII Chapter III 4.1
Single Representative Number (SRN):	DK-AR-000007351
Unique Device Identifier (UDI):	See Attachments
EU Representative:	Global Carehab Holmstrupgaardvej 11 8220 Brabrand Denmark +45 24 65 55 50

complies with the assessment criteria of:

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
Bergeron Health Care

2022-02-24

Date