



October 3, 2019

As Legal Manufacturer

We, 3M Company, 3M Health Care, dba 3M Consumer Health Care,
3M Center, 2510 Conway Ave., Building 275-5W-06, St. Paul, MN 55144 USA
hereby declare under our sole responsibility that the products to which this declaration relates,

Trade Name(s): 3M™ Nexcare™ Cold Pack

3M™ Nexcare™ Cold/Hot Pack

Model Number(s): 2646PEG, 2671PEG

Classification Name: Thermotherapy products

Common Name: Cold/Hot Packs/Compresses

GMDN Code and Term: 37240, Hot/cold therapy pack, reusable
40555, Hot/cold therapy pack, single use

complies with the following standards:

Standard Number	Standard Title
ISO13485:2016	Medical Devices - Quality Management Systems – Requirements for regulatory purposes
ISO14971:2012	Medical Devices – Application of Risk Management to Medical Devices

Sincerely,

Bryan A. Becker, Manager
Regulatory Affairs and Quality
3M Consumer Health Care

14 Oct 2019
Date