

TF0000005 Rev C Technical File

Group: Rehabilitation Equipment Subgroup: Daily Activity Assist Device, Non-measuring Exercise Equipment

4.3 Declaration of Conformity

DECLARATION OF CONFORMITY

Manufacturer:

North Coast Medical Inc.

Address:

780 Jarvis Drive, #100

Morgan Hill, CA 95037

Authorized

MedPass International Ltd

Representative:

95 bis Boulevard Pereire

75017 Paris - France

General Device

Groups:

Subgroup: Daily

Activity Assist

Device

Rehabilitation Equipment

Subgroup: Daily Activity Assist Device		
Family	Item	Description
Dressing Aid	NC28600	Norco Easy Pull Sock Aid
	NC28667	Good Grips Button Hook
	NC65631	Good Grips Shoehorn, 18 in
	NC65632	Good Grips Shoehorn, 24 in
	NC65633	Good Grips Shoehorn, 30 in
Kitchen / Household Aids	NC21003	Writing Bird
	NC92100	Norco Pill Pal
	NC35350	Norco Universal Quad Cuff
	NC65560	Good Grips Weighted Fork
	NC65560-S	Good Grips Weighted Utensils (Set of 5)
	NC65561	Good Grips Weighted Teaspoon
	NC65562	Good Grips Weighted Tablespoon
	NC65564	Good Grips Weighted Souper Spoon
	NC65565	Good Grips Weighted Rocker Knife
	NC65585	Good Grips Serrated Rocker Knife
	NC65590	Good Grips Souper Spoon
	NC65591	Good Grips Fork

Model Numbers:



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	NC65592	Good Grips Rocker Knife
	NC65593	Good Grips Teaspoon
	NC65594	Good Grips Tablespoon
	NC65595	Good Grips Small Spoon
	NC65596	Good Grips Coated Youthspoon
	NC65597	Good Grips Coated Teaspoon
	NC65598	Good Grips Coated Tablespoon
Evaluation	NC12772	Touch-Test Hand Kit
	NC12773	Touch-Test Six Piece Foot Kit
	NC12775-01	Touch-Test Sensory Evaluator (1.65)
	NC12776	Touch Test Two-Point Discriminator
	NC12775-02	Touch-Test Sensory Evaluator (2.36)
	NC12775-03	Touch-Test Sensory Evaluator (2.44)
	NC12775-04	Touch-Test Sensory Evaluator (2.83)
	NC12775-05	Touch-Test Sensory Evaluator (3.22)
	NC12775-06	Touch-Test Sensory Evaluator (3.61)
	NC12775-07	Touch-Test Sensory Evaluator (3.84)
	NC12775-08	Touch-Test Sensory Evaluator (4.08)
	NC12775-09	Touch-Test Sensory Evaluator (4.17)
	NC12775-10	Touch-Test Sensory Evaluator (4.31)
	NC12775-11	Touch-Test Sensory Evaluator (4.56)
	NC12775-12	Touch-Test Sensory Evaluator (4.74)
	NC12775-13	Touch-Test Sensory Evaluator (4.93)
	NC12775-14	Touch-Test Sensory Evaluator (5.07)
	NC12775-15	Touch-Test Sensory Evaluator (5.18)
	NC12775-16	Touch-Test Sensory Evaluator (5.46)
	NC12775-17	Touch-Test Sensory Evaluator (5.88)
	NC12775-18	Touch-Test Sensory Evaluator (6.10)
	NC12775-19	Touch-Test Sensory Evaluator (6.45)
	NC12775-20	Touch-Test Sensory Evaluator (6.65)
	NC12775-99	Touch-Test Sensory Evaluators, Set of 20
	NC70115	Goniometer, 180 deg. Devore Finger
Therapeutic	NC52069	Norco Shoulder Pulley
	NC52080	Norco Economy Shoulder Pulley
	NC95110	Achieva Smart Mirror
	NC70209	Norco Mini Vibrator



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Classification (MDD, Annex VII):Class I, Rule 1

I, the undersigned, hereby ensure and declare with sole responsibility, that our medical devices specified above meet the provisions of Council Directive 93/42/EEC (MDD) as amended by Directive 2007/47/EC which apply to them (Essential Requirements listed in Annex I and the EC Declaration of Conformity listed in Annex II).

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NC65560 -Fork



NC65561 – Weighted Teaspoon



NC65562-Table Spoon



NC65564 -Souper Spoon



NC65565 – Rocker Knife



Grouped set

