

## **DECLARATION OF CONFORMITY**

Identification No.: DER.DOC.072

#### Manufacturer:

DeRoyal Industries Inc. 200 DeBusk Lane Powell, TN 37849 USA

### European authorized representative:

QNET B.V.

Hommerterweg 286, 6436 AM Amstenrade The Netherlands

Product(s): Post-Operative Cervical Collar, Class 1 Non-Sterile, Rule 1

Product Codes: ATTACHED

## The product(s) described above is in conformity with:

Document No.	<u>Title</u>	Edition / Date of issue
L 169; 93/42/EEC	Medical Device Directive, as amended	1993-06-14

## Additional information:

The above identified products, at the stated revisions where applicable, have been reviewed against the relevant provisions of the 93/42/EEC Medical Device Directive, as amended, and have been found to be in compliance with Annex VII as well as the National Laws for countries where these products are made available. These products are also manufactured according to a quality system certified to the ISO 13485; 2003 standard.

(Date of Issue)

Powel TN

Manufacturer signature

Regulatory Affairs

(Function of Manufacturer)

11421000 Cervical Collar, Capital™, W/ Extra Pad Set, Super Short 11422000 Cervical Collar, Capital™, Pad Set, Super Short 11431000 Cervical Collar, Capital™, Pad Set, Super Short 11431000 Cervical Collar, Capital™, Pad Set, Super Short 11433000 Cervical Collar, Capital™, W/ Extra Pad Set, Stout 11433000 Cervical Collar, Capital™, W/ Extra Pad Set, Stout 11433000 Cervical Collar, Capital™, Pad Set, Stout 11443000 Cervical Collar, Capital™, W/ Extra Pad Set, X-Small 11442000 Cervical Collar, Capital™, W/ Extra Pad Set, X-Small 11451000 Cervical Collar, Capital™, Short 11452000 Cervical Collar, Capital™, M/ Extra Pad Set, Short 11461000 Cervical Collar, Capital™, Regular 11461000 Cervical Collar, Capital™, Regular 11471000 Cervical Collar, Capital™, Jarge 11471000 Cervical Collar, Capital™, Infant 0-6 months 11481001 Cervical Collar, Capital™, Infant 0-6 months 11481002 Cervical Collar, Capital™, Infant 0-6 months 11481003 Cervical Collar, Capital™, Infant 0-6 months 11481004 Cervical Collar, Capital™, W/ Extra Pad Set, Infant 0-6 months 11482000 Cervical Collar, Capital™, W/ Extra Pad Set, Infant 0-6 months 11482001 Cervical Collar, Capital™, W/ Extra Pad Set, Infant 0-6 months 11482001 Cervical Collar, Capital™, W/ Extra Pad Set, Infant 0-6 months 11482002 Cervical Collar, Capital™, W/ Extra Pad Set, Child 2-6 years 11482003 Cervical Collar, Capital™, W/ Extra Pad Set, Child 6-12 years 11483000 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years 11483001 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 11483000 Cervical Collar, Capital™, Pad Set, Child 6-12 years 11483000 Cervical Collar, Capital™, Pad Set, Child 6-12 years 11483000 Cervical Collar, Capital™, Pad Set, Child 6-12 years 11483000 Cervical Collar, Capital™, Pad Set, Child 6-12 years 11483000 Cervical Collar, Capital™, Pad Set, Child 6-12 years 11483000 Cervical Collar, Capital™, Pad Set, Child 6-12 years 11483000 Cervical Collar, Capital™, Pad Set, Child 6-12 years 11483000 Cervical Collar, Capital™, Pad Set, Child 6-12 years 11483000		
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11461000 Cervical Collar, Capital™, Regular  11462000 Cervical Collar, Capital™, w/ Extra Pad Set, Regular  11471000 Cervical Collar, Capital™, Large  11472000 Cervical Collar, Capital™, w/ Extra Pad Set, Large  11481000 Cervical Collar, Capital™, Infant 0-6 months  11481001 Cervical Collar, Capital™, Infant 0-6 months  11481002 Cervical Collar, Capital™, Child 2-6 years  11481003 Cervical Collar, Capital™, W/ Extra Pad Set, Infant 0-6 months  11482000 Cervical Collar, Capital™, W/ Extra Pad Set, Infant 0-6 months  11482001 Cervical Collar, Capital™, w/ Extra Pad Set, Infant 6 months-2 years  11482002 Cervical Collar, Capital™, w/ Extra Pad Set, Child 2-6 years  11482003 Cervical Collar, Capital™, w/ Extra Pad Set, Child 6-12 years  11483000 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483001 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483002 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483003 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483004 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11483005 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11483000 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11483000 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Cervical Collar, Inviversal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Short, Collar  11231000 XTW Extended Wear Collar, Adult, Tall, Collar  11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Infant, Short, Collar	11451000	Cervical Collar, Capital™, Short
11462000 Cervical Collar, Capital™, w/ Extra Pad Set, Regular  11471000 Cervical Collar, Capital™, Large  11472000 Cervical Collar, Capital™, w/ Extra Pad Set, Large  11481000 Cervical Collar, Capital™, Infant 0-6 months  11481001 Cervical Collar, Capital™, Infant 6 months-2 years  11481002 Cervical Collar, Capital™, Child 2-6 years  11481003 Cervical Collar, Capital™, W/ Extra Pad Set, Infant 0-6 months  11482000 Cervical Collar, Capital™, w/ Extra Pad Set, Infant 0-6 months  11482001 Cervical Collar, Capital™, w/ Extra Pad Set, Infant 6 months-2 years  11482002 Cervical Collar, Capital™, w/ Extra Pad Set, Child 2-6 years  11482003 Cervical Collar, Capital™, w/ Extra Pad Set, Child 2-6 years  11483000 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483001 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483002 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483003 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483004 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483005 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483006 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Short, Collar  11221000 XTW Extended Wear Collar, Adult, Short, Collar  11231000 XTW Extended Wear Collar, Adult, X-Tall, Collar	11452000	Cervical Collar, Capital™, w/ Extra Pad Set, Short
11471000 Cervical Collar, Capital™, Versura Pad Set, Large  11481001 Cervical Collar, Capital™, Infant 0-6 months  11481001 Cervical Collar, Capital™, Infant 6 months-2 years  11481002 Cervical Collar, Capital™, Child 2-6 years  11481003 Cervical Collar, Capital™, Child 2-6 years  11481000 Cervical Collar, Capital™, Child 6-12 years  11482000 Cervical Collar, Capital™, Wersura Pad Set, Infant 0-6 months  11482001 Cervical Collar, Capital™, Wersura Pad Set, Infant 6 months-2 years  11482002 Cervical Collar, Capital™, Westra Pad Set, Child 2-6 years  11482003 Cervical Collar, Capital™, Westra Pad Set, Child 2-6 years  11483000 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483001 Cervical Collar, Capital™, Pad Set, Infant 0-6 months-2 years  11483002 Cervical Collar, Capital™, Pad Set, Infant 0-6 months-2  11483003 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483004 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483005 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483006 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11483007 Capital Collar, Enhanced powered by Boa® Technology, Collar  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Capital Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Regular, Collar  11231000 XTW Extended Wear Collar, Adult, Regular, Collar  11241000 XTW Extended Wear Collar, Adult, Tall, Collar	11461000	Cervical Collar, Capital™, Regular
11472000 Cervical Collar, Capital™, w/ Extra Pad Set, Large  11481001 Cervical Collar, Capital™, Infant 0-6 months  11481002 Cervical Collar, Capital™, Infant 6 months-2 years  11481003 Cervical Collar, Capital™, Child 2-6 years  11482000 Cervical Collar, Capital™, Child 6-12 years  11482001 Cervical Collar, Capital™, w/ Extra Pad Set, Infant 0-6 months  11482002 Cervical Collar, Capital™, w/ Extra Pad Set, Infant 6 months-2 years  11482003 Cervical Collar, Capital™, w/ Extra Pad Set, Child 2-6 years  11483000 Cervical Collar, Capital™, w/ Extra Pad Set, Child 6-12 years  11483001 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483001 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483002 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483003 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483003 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  1130000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Regular, Collar  11221000 XTW Extended Wear Collar, Adult, Regular, Collar  11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Infant, Short, Collar	11462000	Cervical Collar, Capital™, w/ Extra Pad Set, Regular
11481000 Cervical Collar, Capital™, Infant 0-6 months  11481001 Cervical Collar, Capital™, Infant 6 months-2 years  11481002 Cervical Collar, Capital™, Child 2-6 years  11481003 Cervical Collar, Capital™, Child 6-12 years  11482000 Cervical Collar, Capital™, W/ Extra Pad Set, Infant 0-6 months  11482001 Cervical Collar, Capital™, w/ Extra Pad Set, Infant 6 months-2 years  11482002 Cervical Collar, Capital™, w/ Extra Pad Set, Child 2-6 years  11482003 Cervical Collar, Capital™, w/ Extra Pad Set, Child 2-6 years  11483000 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483001 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483002 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483003 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483003 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  1130000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Short, Collar  11221000 XTW Extended Wear Collar, Adult, Regular, Collar  11231000 XTW Extended Wear Collar, Adult, Tall, Collar  11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Infant, Short, Collar	11471000	Cervical Collar, Capital™, Large
11481001 Cervical Collar, Capital™, Infant 6 months-2 years  11481002 Cervical Collar, Capital™, Child 2-6 years  11481003 Cervical Collar, Capital™, Child 6-12 years  11482000 Cervical Collar, Capital™, w/ Extra Pad Set, Infant 0-6 months  11482001 Cervical Collar, Capital™, w/ Extra Pad Set, Infant 6 months-2 years  11482002 Cervical Collar, Capital™, w/ Extra Pad Set, Child 2-6 years  11482003 Cervical Collar, Capital™, w/ Extra Pad Set, Child 6-12 years  11483000 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483001 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483002 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483003 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483003 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only  11301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Regular, Collar  11231000 XTW Extended Wear Collar, Adult, Regular, Collar  11241000 XTW Extended Wear Collar, Adult, Tall, Collar  11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Infant, Short, Collar	11472000	Cervical Collar, Capital™, w/ Extra Pad Set, Large
11481002 Cervical Collar, Capital™, Child 2-6 years  11481003 Cervical Collar, Capital™, Child 6-12 years  11482000 Cervical Collar, Capital™, w/ Extra Pad Set, Infant 0-6 months  11482001 Cervical Collar, Capital™, w/ Extra Pad Set, Infant 6 months-2 years  11482002 Cervical Collar, Capital™, w/ Extra Pad Set, Child 2-6 years  11482003 Cervical Collar, Capital™, w/ Extra Pad Set, Child 6-12 years  11483000 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483001 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483002 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483003 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Capital Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Short, Collar  11231000 XTW Extended Wear Collar, Adult, Regular, Collar  11241000 XTW Extended Wear Collar, Adult, Tall, Collar  11251000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Adult, X-Tall, Collar	11481000	Cervical Collar, Capital™, Infant 0-6 months
11481003 Cervical Collar, Capital™, Child 6-12 years  11482001 Cervical Collar, Capital™, w/ Extra Pad Set, Infant 0-6 months  11482002 Cervical Collar, Capital™, w/ Extra Pad Set, Lifant 6 months-2 years  11482003 Cervical Collar, Capital™, w/ Extra Pad Set, Child 2-6 years  11482003 Cervical Collar, Capital™, w/ Extra Pad Set, Child 6-12 years  11483000 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483001 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483002 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483003 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only  11301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar  11302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Regular, Collar  11221000 XTW Extended Wear Collar, Adult, Regular, Collar  11231000 XTW Extended Wear Collar, Adult, Tall, Collar  11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Adult, X-Tall, Collar	11481001	Cervical Collar, Capital™, Infant 6 months-2 years
Cervical Collar, Capital™, w/ Extra Pad Set, Infant 0-6 months  11482001 Cervical Collar, Capital™, w/ Extra Pad Set, Infant 6 months-2 years  11482002 Cervical Collar, Capital™, w/ Extra Pad Set, Child 2-6 years  11482003 Cervical Collar, Capital™, w/ Extra Pad Set, Child 6-12 years  11483000 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483001 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483002 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483003 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only  11301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar  11302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Short, Collar  11221000 XTW Extended Wear Collar, Adult, Regular, Collar  11231000 XTW Extended Wear Collar, Adult, Tall, Collar  11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Infant, Short, Collar	11481002	Cervical Collar, Capital™, Child 2-6 years
11482001 Cervical Collar, Capital™, w/ Extra Pad Set, Infant 6 months-2 years  11482003 Cervical Collar, Capital™, w/ Extra Pad Set, Child 2-6 years  11482003 Cervical Collar, Capital™, w/ Extra Pad Set, Child 6-12 years  11483000 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483001 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483002 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483003 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only  11301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Short, Collar  11231000 XTW Extended Wear Collar, Adult, Regular, Collar  11241000 XTW Extended Wear Collar, Adult, Tall, Collar  11251000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Infant, Short, Collar	11481003	Cervical Collar, Capital™, Child 6-12 years
Cervical Collar, Capital™, w/ Extra Pad Set, Child 2-6 years  11482003 Cervical Collar, Capital™, w/ Extra Pad Set, Child 6-12 years  11483000 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483001 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483002 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483003 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only  11301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar  11302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11221000 XTW Extended Wear Collar, Adult, Regular, Collar  11221000 XTW Extended Wear Collar, Adult, Tall, Collar  11231000 XTW Extended Wear Collar, Adult, Tall, Collar  11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Infant, Short, Collar	11482000	Cervical Collar, Capital™, w/ Extra Pad Set, Infant 0-6 months
Cervical Collar, Capital™, w/ Extra Pad Set, Child 6-12 years  11483000 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483001 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483002 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483003 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only  11301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar  11302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Short, Collar  11221000 XTW Extended Wear Collar, Adult, Regular, Collar  11231000 XTW Extended Wear Collar, Adult, Tall, Collar  11241000 XTW Extended Wear Collar, Adult, Tall, Collar  11251000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Infant, Short, Collar	11482001	Cervical Collar, Capital™, w/ Extra Pad Set, Infant 6 months-2 years
11483000 Cervical Collar, Capital™, Pad Set, Infant 0-6 months  11483001 Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  11483002 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483003 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only  11301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar  11302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Regular, Collar  11221000 XTW Extended Wear Collar, Adult, Regular, Collar  11231000 XTW Extended Wear Collar, Adult, Tall, Collar  11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Infant, Short, Collar	11482002	Cervical Collar, Capital™, w/ Extra Pad Set, Child 2-6 years
Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years  1483002 Cervical Collar, Capital™, Pad Set, Child 2-6 years  1483003 Cervical Collar, Capital™, Pad Set, Child 6-12 years  1311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  1312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  13313000 Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only  1301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar  1302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Short, Collar  11221000 XTW Extended Wear Collar, Adult, Regular, Collar  11231000 XTW Extended Wear Collar, Adult, Tall, Collar  11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Infant, Short, Collar	11482003	Cervical Collar, Capital™, w/ Extra Pad Set, Child 6-12 years
11483002 Cervical Collar, Capital™, Pad Set, Child 2-6 years  11483003 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only  11301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar  11302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Short, Collar  11221000 XTW Extended Wear Collar, Adult, Regular, Collar  11231000 XTW Extended Wear Collar, Adult, Tall, Collar  11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Infant, Short, Collar	11483000	Cervical Collar, Capital™, Pad Set, Infant 0-6 months
11483003 Cervical Collar, Capital™, Pad Set, Child 6-12 years  11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar  11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set  11313000 Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only  11301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar  11302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set  11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set  11201000 XTW Extended Wear Collar, Adult, X-Short, Collar  11211000 XTW Extended Wear Collar, Adult, Short, Collar  11221000 XTW Extended Wear Collar, Adult, Regular, Collar  11231000 XTW Extended Wear Collar, Adult, Tall, Collar  11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar  11251000 XTW Extended Wear Collar, Adult, X-Tall, Collar	11483001	Cervical Collar, Capital™, Pad Set, Infant 6 months-2 years
11311000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set 11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set 11313000 Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only 11301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar 11302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set 11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set 11201000 XTW Extended Wear Collar, Adult, X-Short, Collar 11211000 XTW Extended Wear Collar, Adult, Short, Collar 11221000 XTW Extended Wear Collar, Adult, Regular, Collar 11231000 XTW Extended Wear Collar, Adult, Tall, Collar 11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar 11251000 XTW Extended Wear Collar, Infant, Short, Collar	11483002	Cervical Collar, Capital™, Pad Set, Child 2-6 years
11312000 Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set 11313000 Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only 11301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar 11302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set 11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set 11201000 XTW Extended Wear Collar, Adult, X-Short, Collar 11211000 XTW Extended Wear Collar, Adult, Short, Collar 11221000 XTW Extended Wear Collar, Adult, Regular, Collar 11231000 XTW Extended Wear Collar, Adult, Tall, Collar 11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar 11251000 XTW Extended Wear Collar, Adult, X-Tall, Collar	11483003	Cervical Collar, Capital™, Pad Set, Child 6-12 years
11313000 Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only 11301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar 11302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set 11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set 11201000 XTW Extended Wear Collar, Adult, X-Short, Collar 11211000 XTW Extended Wear Collar, Adult, Short, Collar 11221000 XTW Extended Wear Collar, Adult, Regular, Collar 11231000 XTW Extended Wear Collar, Adult, Tall, Collar 11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar 11251000 XTW Extended Wear Collar, Infant, Short, Collar	11311000	Capital Collar, Enhanced powered by Boa® Technology, Collar
11301000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar 11302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set 11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set 11201000 XTW Extended Wear Collar, Adult, X-Short, Collar 11211000 XTW Extended Wear Collar, Adult, Short, Collar 11221000 XTW Extended Wear Collar, Adult, Regular, Collar 11231000 XTW Extended Wear Collar, Adult, Tall, Collar 11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar 11251000 XTW Extended Wear Collar, Infant, Short, Collar	11312000	Capital Collar, Enhanced powered by Boa® Technology, Collar & Pad Set
11302000 Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set 11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set 11201000 XTW Extended Wear Collar, Adult, X-Short, Collar 11211000 XTW Extended Wear Collar, Adult, Short, Collar 11221000 XTW Extended Wear Collar, Adult, Regular, Collar 11231000 XTW Extended Wear Collar, Adult, Tall, Collar 11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar 11251000 XTW Extended Wear Collar, Infant, Short, Collar	11313000	Capital Collar, Enhanced powered by Boa® Technology, Pad Set Only
11303000 Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set 11201000 XTW Extended Wear Collar, Adult, X-Short, Collar 11211000 XTW Extended Wear Collar, Adult, Short, Collar 11221000 XTW Extended Wear Collar, Adult, Regular, Collar 11231000 XTW Extended Wear Collar, Adult, Tall, Collar 11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar 11251000 XTW Extended Wear Collar, Infant, Short, Collar	11301000	Cervical Collar, Universal XTW powered by Boa® Technology, Collar
11201000 XTW Extended Wear Collar, Adult, X-Short, Collar 11211000 XTW Extended Wear Collar, Adult, Short, Collar 11221000 XTW Extended Wear Collar, Adult, Regular, Collar 11231000 XTW Extended Wear Collar, Adult, Tall, Collar 11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar 11251000 XTW Extended Wear Collar, Infant, Short, Collar	11302000	Cervical Collar, Universal XTW powered by Boa® Technology, Collar & Pad Set
11211000XTW Extended Wear Collar, Adult, Short, Collar11221000XTW Extended Wear Collar, Adult, Regular, Collar11231000XTW Extended Wear Collar, Adult, Tall, Collar11241000XTW Extended Wear Collar, Adult, X-Tall, Collar11251000XTW Extended Wear Collar, Infant, Short, Collar	11303000	Cervical Collar, Universal XTW powered by Boa® Technology, Pad Set
11221000XTW Extended Wear Collar, Adult, Regular, Collar11231000XTW Extended Wear Collar, Adult, Tall, Collar11241000XTW Extended Wear Collar, Adult, X-Tall, Collar11251000XTW Extended Wear Collar, Infant, Short, Collar	11201000	XTW Extended Wear Collar, Adult, X-Short, Collar
11231000XTW Extended Wear Collar, Adult, Tall, Collar11241000XTW Extended Wear Collar, Adult, X-Tall, Collar11251000XTW Extended Wear Collar, Infant, Short, Collar	11211000	XTW Extended Wear Collar, Adult, Short, Collar
11241000 XTW Extended Wear Collar, Adult, X-Tall, Collar 11251000 XTW Extended Wear Collar, Infant, Short, Collar	11221000	XTW Extended Wear Collar, Adult, Regular, Collar
11251000 XTW Extended Wear Collar, Infant, Short, Collar	11231000	XTW Extended Wear Collar, Adult, Tall, Collar
	11241000	XTW Extended Wear Collar, Adult, X-Tall, Collar
11261000 XTW Extended Wear Collar, Infant, Reguar, Collar	11251000	XTW Extended Wear Collar, Infant, Short, Collar
	11261000	XTW Extended Wear Collar, Infant, Reguar, Collar

11271000	XTW Extended Wear Collar, Child, Tot, Collar
11281000	XTW Extended Wear Collar, Child, Short, Collar
11291000	XTW Extended Wear Collar, Child, Regular, Collar
11202000	XTW Extended Wear Collar, Adult, X-Short, Collar & Pad Set
11212000	XTW Extended Wear Collar, Adult, Short, Collar & Pad Set
11222000	XTW Extended Wear Collar, Adult, Regular, Collar & Pad Set
11232000	XTW Extended Wear Collar, Adult, Tall, Collar & Pad Set
11242000	XTW Extended Wear Collar, Adult, X-Tall, Collar & Pad Set
11252000	XTW Extended Wear Collar, Infant, Short, Collar & Pad Set
11262000	XTW Extended Wear Collar, Infant, Regular, Collar & Pad Set
11272000	XTW Extended Wear Collar, Child, Tot, Collar & Pad Set
11282000	XTW Extended Wear Collar, Child, Short, Collar & Pad Set
11292000	XTW Extended Wear Collar, Child, Regular, Collar & Pad Set
11226000	Cervical Collar, CTO, Adult, Regular
11216000	Cervical Collar, CTO, Adult, Short
11236000	Cervical Collar, CTO, Adult, Tall
11246000	Cervical Collar, CTO, Adult, X-Tall
11256000	Cervical Collar, CTO, Pediatric
11816900	Rigid Cervical Collar, 1-Piece
11845005	Rigid Cervical Collar, Molded
11845006	Rigid Cervical Collar, Molded
11845007	Rigid Cervical Collar, Molded
11883005	Rigid Cervical Collar, Molded
11883006	Rigid Cervical Collar, Molded
11901001	Rigid Cervical Collar, Molded
11902002	Rigid Cervical Collar, Molded
401N12	Cervical Collar, Capital™, Super Short
406N16	Cervical Collar, Capital™, w/ Extra Pad Set, Super Short
401N22	Cervical Collar, Capital™, Stout
406N26	Cervical Collar, Capital™, w/ Extra Pad Set, Stout
402N12	Cervical Collar, Capital™, XS
499N31	Cervical Collar, Capital™, w/ Extra Pad Set, XS
402N22	Cervical Collar, Capital™, Short
498N32	Cervical Collar, Capital™, w/ Extra Pad Set, Short
403N13	Cervical Collar, Capital™, Regular
497N33	Cervical Collar, Capital™, w/ Extra Pad Set, Regular
403N23	Cervical Collar, Capital™, Large
497N34	Cervical Collar, Capital™, w/ Extra Pad Set, Large
404N14	Cervical Collar, Capital™, 0-6 months
404N24	Cervical Collar, Capital™, 6 months - 2 years
405N15	Cervical Collar, Capital™, 2-6 years
405N25	Cervical Collar, Capital™, 6-12 years
499N41	Cervical Collar, Capital™, w/ Extra Pad Set, 0-6 months

### Attachment to DER.DOC.072

498N42	Cervical Collar, Capital™, w/ Extra Pad Set, 6 months - 2 yrs
497N43	Cervical Collar, Capital™, w/ Extra Pad Set, 2-6 years
497 <b>N</b> 44	Cervical Collar, Capital™, w/ Extra Pad Set, 6-12 years
14-115A-01	Cervical Collar, Capital™, w/ Extra Pad Set, Super Short
14-115A-02	Cervical Collar, Capital™, w/ Extra Pad Set, Stout
14-115A-03	Cervical Collar, Capital™, w/ Extra Pad Set, X-Small
14-115A-04	Cervical Collar, Capital™, w/ Extra Pad Set, Short
14-115A-05	Cervical Collar, Capital™, w/ Extra Pad Set, Regular
14-115A-06	Cervical Collar, Capital™, w/ Extra Pad Set, Large
1107SSPP	Cervical Collar, Capital™, Super Short
1107SSSPP	Cervical Collar, Capital™, w/ Extra Pad Set, Super Short
1107STPP	Cervical Collar, Capital™, Stout
1107STSPP	Cervical Collar, Capital™, w/ Extra Pad Set, Stout
1107XSPP	Cervical Collar, Capital™, XS
1107XSSPP	Cervical Collar, Capital™, w/ Extra Pad Set, XS
1107SHPP	Cervical Collar, Capital™, Short
1107SHSPP	Cervical Collar, Capital™, w/ Extra Pad Set, Short
1107RPP	Cervical Collar, Capital™, Regular
1107RSPP	Cervical Collar, Capital™, w/ Extra Pad Set, Regular
1107LPP	Cervical Collar, Capital™, Large
1107LSPP	Cervical Collar, Capital™, w/ Extra Pad Set, Large
1108ZPP	Cervical Collar, Capital™, 0 - 6 Months
1108SPP	Cervical Collar, Capital™, 6 Months - 2 Years
1108TPP	Cervical Collar, Capital™, 2 - 6 Years
1108WPP	Cervical Collar, Capital™, 6-12 Years
1108ZSPP	Cervical Collar, Capital™, w/ Extra Pad Set, 0-6 Months
1108SSPP	Cervical Collar, Capital™, w/ Extra Pad Set, 6 Months - 2 Years
1108TSPP	Cervical Collar, Capital™, w/ Extra Pad Set, 2-6 Years
1108WSPP	Cervical Collar, Capital™, w/ Extra Pad Set, 6-12 Years

# **Document Change Control**

Date	Reason for Change
9 <sup>th</sup> Sept 2015	Addition of Product for CHANECO
	Addition of SKUs (4XXNXX) for Ascension
	Addition of SKUs (14-115A-XX) for Continuum
16 <sup>th</sup> Nov 2015	Addition of SKUs (110xxxxxx) for Premier Pro
	Addition of SKUs Universal XTW Collar