

## **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:**

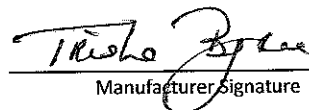
<u>Document No.</u>	<u>Title</u>	<u>Edition / Date of issue</u>
L 169; 93/42/EEC	Medical Device Directive, as amended	1993-06-14

### **Additional information:**

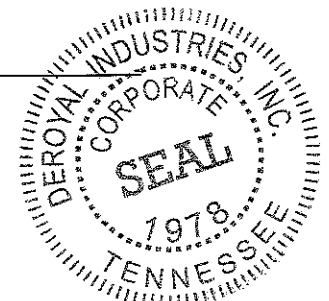
The above identified products, at the stated revisions where applicable, have been reviewed against the relevant provisions of the 93/42/EEC Medical Device Directive, as amended, and have been found to be in compliance with Annex VII as well as the National Laws for countries where these products are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

16<sup>th</sup> Nov, 2015  
(Date of Issue)

Powell, TN  
(Place of Issue)

  
Manufacturer Signature

Regulatory Affairs  
(Function of Manufacturer)



11421000	Cervical Collar, Capital™, Super Short
11422000	Cervical Collar, Capital™, w/ Extra Pad Set, Super Short
11423000	Cervical Collar, Capital™, Pad Set, Super Short
11431000	Cervical Collar, Capital™, Stout
11432000	Cervical Collar, Capital™, w/ Extra Pad Set, Stout
11433000	Cervical Collar, Capital™ Pad Set, Stout
11441000	Cervical Collar, Capital™, X-Small
11442000	Cervical Collar, Capital™, w/ Extra Pad Set, X-Small
11443000	Cervical Collar, Capital™ Pad Set, X-Small
11451000	Cervical Collar, Capital™, Short
11452000	Cervical Collar, Capital™, w/ Extra Pad Set, Short
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 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, 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
11261000	XTW Extended Wear Collar, Infant, Regular, Collar

## Attachment to DER.DOC.072

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

498N42	Cervical Collar, Capital™, w/ Extra Pad Set, 6 months - 2 yrs
497N43	Cervical Collar, Capital™, w/ Extra Pad Set, 2-6 years
497N44	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
1107STSPPP	Cervical Collar, Capital™, w/ Extra Pad Set, Stout
1107XSPP	Cervical Collar, Capital™, XS
1107XSPP	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
1108TTPP	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