



EU MDR DECLARATION OF CONFORMITY

We Neo G Limited hereby declare under our sole responsibility that the Products described in this document are in conformance with the relevant and applicable general safety and performance requirements and provisions according to European Communities Council Regulation 2017/745 concerning Medical Devices amending Directive 2001/83/EC, Regulation (EC) 178/2002 and Regulation 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and the CE Mark may be affixed.

Legal Manufacturer:	Building A, Knaresborough Technology Park, Manse Lane, Knaresborough, North Yorkshire, HG5 8LF, England.
General Product Name & Variants:	As per Appendix II (This document) – Product Listing/Schedule
MDR Classification:	Class I
SRN number	GB-MF-000004603
Notified Body:	Not applicable for class I
EU Authorised Representative:	European Healthcare & Device Solutions (Ireland) Ltd., Stratton House, Bishopstown Road, Bishopstown, Cork T12 Y9TC, Ireland
MDR Conformity Assessment Route:	EC Declaration of Conformity in accordance with Annexes II & III + Article 19 of the Medical Device Regulation.

Name Gareth Deacon

Signed 

Position Senior Technical Manager

Issue Date 2nd February 2024

Expiry Date 2nd February 2026

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.



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Registered in England No: 5182055. **VAT no:** 856627783.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
2017/745	Council Regulation 2017/745 concerning Medical Devices amending Directive 2001/83/EC, Regulation (EC) 178/2002 and Regulation 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices

Appendix II – Product Listing/Schedule

1.1. Neo G - Variable Compression Supports (VCS) Range

Basic UDI-DI	GMDN	Reference	Device Description
50630008812D	41455	881	Wrist Band
50630008822F	41455	882	Wrist Support
50630008832H	41455	883	Tennis/Golf Elbow Strap
50630008842K	41472	884	Closed Knee Support
50630008852M	41472	885	Open Knee Support
50630008862P	41472	886	Patella Band
5063000887-V7C	41472	887-V	Ankle Support
50630008872R	41472	887	Ankle Support with Figure of 8 Strap
50630008882T	44952	888	Thigh and Hamstring Support
50630008892V	41442	889	Waist/Back Support
50630008912G	41442	891	Back Brace
50630008922J	44952	892	Calf/Shin Splint Support
50630008932L	41472	893	Stabilized Open Knee Support
50630008942N	41472	894	Stabilized Hinged Open Knee Support
50630008952Q	41455	895	Stabilized Wrist Brace (R/L)
50630008962S	41455	896	Shoulder Support (R/L)
50630008992Y	41455	899	Elbow Support
50630008802B	41455	880	Thumb Brace
50630008542A	41472	854	Laced Ankle Support
50630008142T	41472	814	Ankle Brace with Air Pad
506300081622	41472	816	Ankle Brace with Gel Pad
50630008762L	41472	876	ITB Strap
50630008782Q	41455	878	Easy-Fit Thumb Brace
5063000888BJY	44952	888B	Groin Support
50630008902E	41442	890	Back Brace with Power Straps
50630008972U	41472	897	Stabilized Ankle Support with Figure of 8 Strap
50630008982W	41472	898	Adjusta-Fit Hinged Open Knee Support
5063000309Z9	41455	309	Easy-Fit Wrist Brace (S - L)
5063000309UHW	41455	309U	Easy-Fit Wrist Brace Universal
5063000760ZV	41455	760	Tennis/Golf Elbow Clasp
50630009962X	41455	996	Stabilized Wrist & Thumb Brace (L/R)
5063000185ZF	41442	185	Easy-Fit Back Brace
50630008562E	41026	856	Sacroiliac Belt with Power Straps
50630008682M	41472	868	Adjusta-Fit Hinged Knee Brace
50630008792S	41455	879	Universal Wrist Brace
50630009932R	41472	993	Open Knee Brace
50630006962G	41473	696	Easy Fit Shoulder Support
5063000OS189	41475	OS1	Back Brace with Lumbar support

1.2. Neo G - Airflow Range

Basic UDI-DI	GMDN	Reference	Device Description
50630007212K	41455	721	Airflow Elbow Support (S - XL)
50630007222M	41455	722	Airflow Wrist & Thumb Support (S - L)
50630007232P	44952	723	Airflow Calf /Shin Support (S - XL)
50630007242R	41472	724	Airflow Ankle Support (S - XL)

5063000725ZT	41472	725	Airflow Knee Support (S - XL)
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1.3. Neo G – Airflow Plus Range

Basic UDI-DI	GMDN	Reference	Device Description
5063000453ZH	41472	453	Airflow Plus Stabilized Knee Support (XS - XXL) silicone
5063000456ZP	41472	456	Airflow Plus Ankle Support (S - XL)
5063000458ZT	41455	458	Airflow Plus Elbow Support (S - XL)

1.4. Neo G - Rehab Xcelerator (RX) Range

Basic UDI-DI	GMDN	Reference	Device Description
5063000163Z5	41472	163	RX Stabilized Knee Support (S - XXL)
5063000164Z7	41472	164	RX Stabilized Ankle Support (S - XL)
5063000160YX	41455	160	RX Tennis/Golf Elbow Strap
5063000161YZ	41442	161	RX Stabilized Back Brace (S - XL)
5063000165Z9	41455	165	RX Wrist Brace (S - L)
50630008552C	41026	855	RX Sacroiliac Belt (S - XL)

1.5. Neo G - Bunion Correction Systems

Basic UDI-DI	GMDN	Reference	Device Description
5063000511Z6	61907	511	Bunion - Hallux Valgus Night Splint (R/L Side)
5063000510Z4	61907	510	Bunion - Soft Support (R/L Side, Pair)

1.6. Neo G - Hernia Supports

Basic UDI-DI	GMDN	Reference	Device Description
5063000601Z8	47218	601	Lower Hernia Support (Left or Right) (S – L)
5063000602ZA	47218	602	Double Lower Hernia Support (S – L)
5063000134YW	47218	134	Upper Abdominal Hernia Support

1.7. Neo G - Cervical Collars

Basic UDI-DI	GMDN	Reference	Device Description
5063000203YQ	41039	203	Soft Collar (S-XXL)
5063000204YS	41039	204	Nelson Collar (S-L)
5063000205YU	41039	205	Philadelphia Collar
5063000208Z2	41039	208	Easy-Fit Neck Brace

1.8. Neo G - Angora & Wool Warmers and Supports

Basic UDI-DI	GMDN	Reference	Device Description
5063000114YQ	44952	114	Angora Wool Waist/Back Warmer & Support (S - XL)
5063000805ZS	44952	805	Angora Wool Knee Warmer & Support (S - XL)

1.9. Neo G Knee and Leg Immobilizers

Basic UDI-DI	GMDN	Reference	Device Description
5063000320YV	41472	320	Knee Immobilizer (40cm, 50cm, 60cm, 70cm)
50630008582J	41472	858	Post Operative Knee Brace

1.10. Neo G - Arm Slings & Immobilizers

Basic UDI-DI	GMDN	Reference	Device Description
5060247393037D	41455	303	Comfort Sponge Arm Sling
5060247399979E	41455	997	Airflow Breathable Arm Sling
5060247393027B	41455	302	Cotton Arm Sling (S - L)
5060247393047F	41455	304	Comfort Shoulder Immobilizer
5060247398598Z	41455	859	Post Operative Elbow Brace (R/L)
50630006972J	41474	697	Easy Fit Arm Sling

1.11. Neo G - Hand Rehabilitation

Basic UDI-DI	GMDN	Reference	Device Description
5063000336ZC	42050	336	Easy-Fit Finger Splint (S - XL)
5063000350Z6	34200	350	Hand Rehabilitation Fist Shaped
5063000560RJ9	34200	560R	Hand Rehab Therapy Silicone Ball - Red = Hard (resistance)
5063000560BH9	34200	560B	Hand Rehab Therapy Silicone Ball - Blue = Medium (resistance)
5063000560GHK	34200	560G	Hand Rehab Therapy Silicone Ball - Green = Soft (resistance)
5063000396ZW	16500	396	Comfort / Relief Arthritis Gloves (XS – XL)

1.12. Neo G – Open Toe Compression Hosiery

Basic UDI-DI	GMDN	Reference	Device Description
5063000911ZS	42811	911	Open Toe Thigh High Compression Hosiery (20-30 mmHg) (S - XXL)
50630009712F	42811	971	Open Toe Thigh High Compression Hosiery (20-30 mmHg) (S - XXXXL)
5063000912ZU	42811	912	Open Toe Knee High Compression Hosiery (20-30 mmHg) (S - XXL)
5063000913ZW	42811	913	Open Toe Pantyhose Compression Hosiery (20-30 mmHg) (S - XXL)
50630009732K	42811	973	Open Toe Pantyhose Compression Hosiery (20-30 mmHg) (S - XXXXL)
50630009722H	42811	972	Therapeutic Knee High (Open Toe)
5063000910ZQ	42811	910	Anti-Embolism Knee High (Open Toe)
50630009092A	42811	909	Anti-Embolism Thigh High (Open Toe)

1.13. Neo G – Closed Toe Compression Hosiery

Basic UDI-DI	GMDN	Reference	Device Description
5063000921ZV	42811	921	Closed Toe Thigh High Compression Hosiery (20-30 mmHg) (S - XXL)
5063000904ZV	42811	904	Closed Toe Thigh High Compression Hosiery (20-30 mmHg) (S - XXXXL)
506300092222	42811	922	Closed Toe Knee High Compression Hosiery (20-30 mmHg) (S - XXL)
506300092324	42811	923	Closed Toe Pantyhose Compression Hosiery (20-30 mmHg) (S - XXL)
5063000920ZT	42811	920	Men's Compression Socks (20-30 mmHg) (S - XXL)
50630009702D	42811	970	Travel & Flight Compression Socks (S - XL)

5063000930ZW	42811	930	Energizing Daily Wear Men's Socks (S - XL)
506300093225	42811	932	Energizing Daily Wear Knee Highs (S - XL)
5063000932SH8E	42811	932SH	Energizing Comfort Sheer Knee Highs
5063000931SH89	42811	931SH	Energizing Thigh High
5063000933SH8K	42811	933SH	Comfort Sheer Pantyhose
5063000930ST8U	42811	930ST	Classic Sock
506300090522	42811	905	Therapeutic Knee High (Closed Toe)
5063000903ZT	42811	903	Therapeutic Pantyhose (Closed Toe)
5063000910CT6W	42811	910CT	Anti-Embolism Knee High (Closed Toe)
5063000909CT84	42811	909CT	Anti-Embolism Thigh High (Closed Toe)
506300094024	42811	940	Energizing Active Sock
506300094126	42811	941	Everyday Comfort Sheer Thigh High
506300094228	42811	942	Everyday Comfort Sheer Knee high
50630009432A	42811	943	Everyday Comfort Sheer Pantyhose

1.14. Neo G - Kids Variable Compression Supports (VCS) Range

Basic UDI-DI	GMDN	Reference	Device Description
5063000885KK9	41472	885K	Kids Open Knee Support (VCS range)
5063000894KKB	41472	894K	Kids Hinged Open Knee Support (VCS range)
5063000882KJY	41455	882K	Kids Wrist Support (VCS range)
5063000887KKF	41472	887K	Kids Ankle Support with Figure of 8 Strap (VCS range)
5063000895KKE	41455	895K	Kids Stabilized Wrist Brace (VCS range) (L/R)

1.15. Neo G - Kids Leg Immobilizer

Basic UDI-DI	GMDN	Reference	Device Description
5063000320KGR	41472	320K	Kids Knee Immobilizer (20cm ,25cm ,30cm ,35cm)

1.16. Neo G - Kids Cervical Collars

Basic UDI-DI	GMDN	Reference	Device Description
5063000203KGH	41039	203K	Kids Soft Collar
5063000204KGL	41039	204K	Kids Nelson Collar
5063000205KGP	41039	205K	Kids Philadelphia Collar

1.17. Neo G Kids Waist/Back/Posture Supports

Basic UDI-DI	GMDN	Reference	Device Description
5063000138KH8	13810	138K	Kids Clavicle Brace (POSTUREX)
5063000130KGG	41442	130K	Kids Dorsolumbar Support/Brace

1.18. Neo G Kids Arm Sling & Immobilizer

Basic UDI-DI	GMDN	Reference	Device Description
5063000303KGQ	41455	303K	Kids Comfort Sponge Arm Sling
5063000304KGT	41455	304K	Kids Comfort Shoulder Immobilizer
5063000859KK6	41455	859K	Kids Post Operative Elbow Brace

1.19. Neo G Adult Waist/Back/Posture/Clavicle Supports

Basic UDI-DI	GMDN	Reference	Device Description
506300099833	13810	998	Light Clavicle/Posture Support

5063000130YN	41442	130	Dorsolumbar Support/Brace
5063000131YQ	41442	131	Lumbosacral Support/Brace
5063000135YY	41442	135	Lumbostad Support/Brace
5063000138Z6	13810	138	Clavicle Brace (POSTUREX)
5063000139Z8	47217	139	Pregnancy Support Belt
5063000145Z3	41442	145	Light Lombostad Support/Brace

1.20. Neo G AFOs - Ankle Foot Orthoses

Basic UDI-DI	GMDN	Reference	Device Description
50630008642D	41472	864	Anti-Rotation AFO Footguard (For use with Left or Right Foot) (S – L)
50630008652F	41472	865	Reflex AFO/Drop foot (L/R) (S - XL)

1.21. Neo G Reusable Hot & Cold Therapy

Basic UDI-DI	GMDN	Reference	Device Description
50630003DH/C1YB	37240	3DH/C1	Hot & Cold Therapy Disc
50630003DH/C3YF	37240	3DH/C3	Hot & Cold Therapy Pack

1.22. Neo G Footcare Range

Basic UDI-DI	GMDN	Reference	Device Description
5063000474ZR	41472	474	Plantar Fasciitis Daily Support and Relief (S – XXL)
5063000591ZW	41575	591	Neothotics Full Length Insoles (S-XXL)
506300059325	41575	593	Neothotics ¾ Length Insoles (S-XXL)
506300059427	36295	594	Neothotics Heel Cushions (S-XL)
506300059529	36295	595	Neothotics REACT Insoles
50630005962B	36295	596	Neothotics Pro-Flex Full Length Slimline Insoles
50630005972D	36295	597	Neothotics Pro-Expert Full Length Orthotic Insoles
50630005982F	36295	598	Neothotics Pro-Expert 3/4 Length Orthotic Insoles
50630005992H	36295	599	Neothotics Pro-Expert Slim-Fit ¾ Length Insoles
50630008632B	41472	863	Drop Foot (S - L)

1.23. Neo G Silicopad Product Range

Basic UDI-DI	GMDN	Reference	Device Description
5063000542ZH	41575	542	Silicone Full Length Insole (XS – XL)
5063000543ZK	41575	543	Silicone 3/4 Length Insole (XS – XXL)
5063000544ZM	36295	544	Silicone Heel Spur (S – XL)
5063000545ZP	36295	545	Silicone Toe Spreaders (S – L)
5063000547ZT	36295	547	Silicone Ring (S – L)
5063000548ZV	36295	548	Silicone Toe Caps (S – L)
506300054922	41575	549	Silicone Forefoot Insole
5063000550ZG	13565	550	Silicone Bunion Shield
5063000553ZN	36295	553	Silicone Toe Crest With Loop (R/L)
5063000582ZV	36295	582	Adhesive Silicone Medial & Lateral Wedge (S – XL)
506300058424	36295	584	Adhesive Silicone Heel Spur (S – XL)
50630005892E	36295	589	Adhesive Silicone Metatarsal Pad (S - L)
5063000590ZU	41575	590	Adhesive Silicone Longitudinal Arch Support (S – L)

1.24. Neo G Injury and Recovery Tape

Basic UDI-DI	GMDN	Reference	Device Description
5063000NKT1-RBBF4	34831	NKT1-RBB	NeoTape Lifestyle & Sports Therapy Aid (5m)
5063000NCT2SQ	63279	NCT2	NeoTape – Cohesive Bandage

1.25. Neo G Active Range

Basic UDI-DI	GMDN	Reference	Device Description
506300075323	41455	753	Active Elbow Support
506300075425	41472	754	Active Ankle Support
506300075527	41472	755	Active Knee Support
506300075629	41455	756	Active Wrist & Thumb Support
50630007572B	44952	757	Active Calf /Shin Support
50630007582D	44952	758	Active Thigh Support
50630007592F	41455	759	Active Shoulder Support
50630007792M	41455	779	Active Adjusta Fit Wrist Brace
50630007822A	41455	782	Active Adjusta Fit Wrist Support
50630007832C	41479	783	Active Adjusta Fit Tennis/Golf Elbow Strap
50630007852G	41472	785	Active Adjusta Fit Knee Support
5063000787VKW	41472	787V	Active Adjusta Fit Ankle Support
50630007872L	41476	787	Active Adjusta Fit ankle support with Fig of 8 strap
5063000788BJR	41478	788B	Active Adjusta Fit Groin Support
506300079029	41442	790	Active Adjusta Fit Back Brace
50630007932F	41472	793	Active Adjusta Fit Knee Brace
50630007962M	41455	796	Active Adjusta Fit Shoulder Support
50630007972P	41477	797	Active Adjusta Fit Stabilized Ankle Support with Figure of 8 Strap
50630007992T	41455	799	Active Adjusta Fit Elbow support
50630007652A	41472	765	Active Plus Stabilized Knee Support
506300076428	41472	764	Active Plus Ankle Support
506300076324	41472	763	Active Plus Achilles Tendon Support
506300076226	41455	762	Active Plus Elbow Support

1.26. Neo G Diabetic Socks

Basic UDI-DI	GMDN	Reference	Device Description
50630009762R	59075	976	Neo G Diabetic Sock (Short)
50630009782V	59075	978	Neo G Diabetic Sock (Long)

Appendix 3 - Version History

Version	Compiled by	Date	Description
13	Gareth Deacon	17/11/2020	Addition of Basic UDI-DI
14	Gareth Deacon	17/12/2020	Addition of EU Rep & GMDN no.
15	Gareth Deacon	22/03/2021	Transfer onto new template
16	Gareth Deacon	17/09/2021	Addition of review date. Addition of Pro Expert and Pro Flex to the Neothotics Range. Update of Open & Closed toe Hosiery range. Update of Active Range.
17	Gareth Deacon	25/01/2022	Update of all Basic UDI-DI codes Addition of SRN number
18	Gareth Deacon	17/04/2023	Correction of Conformity Assessment Route Update with new products added.
19	Gareth Deacon	22/05/2023	Update with new products added.
20	Gareth Deacon	02/01/2024	Update with new products added.
21	Gareth Deacon	11/01/2024	Removal of NKT1-RPW
22	Gareth Deacon	02/02/2024	Update with new products added.