

DECLARATION OF CONFORMITY



We, the company

MDH LTD.
90-349 LODZ
UL. KS. W. TYMIENIECKIEGO 22/24
POLAND

Hereby declare on our own responsibility declared that the medical devices listed above, marked CE are medical devices of first class, rule 1, in accordance with annex IX of directive 93/42/EEC.

They definite fundamental claims grant in to annex I and answer to primary requirements of the directive 93/42/EEC, annex VII and conform with harmonized standards applied:

EN ISO 13485:2012

EN ISO 14971:2012

EN 980:2008

EN 1041:2008

EN 22523:2006

President
Tadeusz Baczyński

mdh sp. z o.o.
90-349 Łódź
ul. Ks. W. Tymienieckiego 22/24
NIP 728-22-95-492 REGON 472253652

(Stamp company)

20.02.2014

DECLARATION OF CONFORMITY



Brand	Catalogue number	Product	Size
Qmed	DRQA0B	NT-Bac Collar	Height 29.5-44.6 cm Circumference 7-12 cm
Qmed	DRQA0C	NT-Bac Plus Collar	Height 29.5-44.6 cm Circumference 7-12 cm
Qmed	DRQA0A	Orthopaedic Collar	S-L
Qmed	DRQC	Orthopaedic Vest	
Qmed Active Line	DRQJ0B	Acromed	1-5
Qmed Silver Line	QSM00020 QSM00030 QSM00040 QSM00050	Arm Abduction Orthosis	S-XL
Qmed Silver Line	QSM00090	Sling with stabilization strap	Universal
Qmed	DRQG0A	4-Arm non-woven fabric sling	S-L
Qmed Active Line	DRQF0G	Elbow Support	1-5
Qmed Active Line	DRQF0F	Prohand	Universal
Qmed	DRQF0B	WHO-Stab Plus	S - L
Qmed	DRQF0C	WHOSP-F	S - L
Qmed	DRQF0D	WHOSP-FT	S - L
Qmed Silver Line	QBE01020 QBE01030 QBE01040 QBE01050 QBE01060	LS Support	S - XXL
Qmed	DRQH0A	Spinactive	1-6
Qmed	DRQH0K	Spinactive-LSII	1-6
Qmed Active Line	DRQH0I	Spincare Frame	1-5
Qmed	DRQH0B	Spincare Flex Spincare Flex II	1-6
Qmed	DRQH1B	Spincare Cross	S-XXL
Qmed	DRQH0C	Spincare Rigid	1-6

DECLARATION OF CONFORMITY



Brand	Catalogue number	Product	Size
Qmed	DRQH0J	Spincare Rigid II	1-5
Qmed	DRQH2J	Spincare High	S-XXL
Qmed	DRQH0P	Spincare High Plus	S-XXL
Qmed	DRQB	Hyperextension Jewett Type	S-L
Qmed Active Line	QSM00091	Clavicle Support	Universal
Qmed	DRQH0L	Spincare Extensor	1-5
Qmed Silver Line	QKN00091	Patella Tendon Strap	Universal
Qmed Silver Line	QKN01021 QKN01031 QKN01041 QKN01051	Stabilizing Knee Brace	S-XL
Qmed	DRQI0C	Motive	1-5
Qmed Silver Line	QKM1022 QKM1032 QKM1042 QKM1052 QKM1062	Shin and Thigh Brace	S-XXL
Qmed Silver Line	QKN04020 QKN04030 QKN04040 QKN04050	Stabilizing Knee Brace	S-XL
Qmed Silver Line	QKM06090	Post-operative knee brace with hinge	Universal
Qmed	DRQI5A	First	S-L
Qmed Active Line	DRQI0A	Anmove	1-6
Qmed Active Line	DRQI0H	AFO-Soft	S-L
Qmed Silver Line	QAR03091	Stabilizing Ankle Brace (Pneumatic Gel)	Universal
Qmed	DRQI3H	AFO-Walker	S-XL

DECLARATION OF CONFORMITY



Brand	Catalogue number	Product	Size
Qmed Silver Line	QAM04010 QAM04020 QAM04030 QAM04040 QAM04050	Foot and Shin Brace	XS-XL
Qmed Silver Line	QAM04011 QAM04021 QAM04031 QAM04041 QAM04051	Foot and Shin Brace (Pneumatic)	XS-XL
Qmed	DRQI3A	AFO-Night	S-L
Qmed	DRQI1A	AFO-Fit	S-XL
Qmed	DRQI0B	Hip Orthosis	S-XL
Qmed Silver Line	Q420006	Wrist and Forearm Splint	XS-L
Qmed Silver Line	QEM06191	Post OP Elbow Brace	Universal
Qmed Silver Line	Q62011	Foot Shin Brace	S-XL
Qmed Silver Line	QKM06091	Post OP Knee Brace	Universal
Qmed	DRQE0D	Lumbar Support	Universal
Qmed 3D Line	DRQI5B	Knee Orthosis	S-XL
Qmed 3D Line	DRQI5C	Ankle Stabilizing Orthosis	S-XL
Qmed 3D Line	DRQF5C	Elbow Orthosis	S-XL
Qmed 3D Line	DRQF5B	Wrist Stabilizing Brace	S-XL
Qmed 3D Line	DRQF5A	Wrist Stabilizer	S-XL
Qmed Active Line	DRQI0M	Kneemotion II	1-6
Qmed	DRQJ0A	Arm abduction orthosis	S-L

DECLARATION OF CONFORMITY



Brand	Catalogue number	Product	Size
Qmed	DRQI3S	ROM Knee Brace Covering Shin and Thing	Universal
Qmed	DRQI0D	S-move	1-5