



COOK IRELAND LTD.  
 O'HALLORAN ROAD  
 NATIONAL TECHNOLOGY PARK  
 LIMERICK, V94 N8X2, IRELAND  
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 WWW.COOKMEDICAL.EU

Identification of the device(s) <sup>1</sup> (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period	Substitute Device(s) (if applicable)
ZFV6-80-9-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-9-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-9-6.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-9-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-9-10.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-9-12.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-9-14.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-10-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-10-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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ZFV6-80-10-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-10-6.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-10-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-10-10.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-10-12.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-10-14.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-5-17.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-5-20.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-6-17.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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ZFV6-80-7-17.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-7-20.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-8-17.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-80-8-20.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-125-5-17.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-125-5-20.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-125-6-17.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZFV6-125-6-20.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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EVO-8-9-4-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
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ZIV5-80-7-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-80-7-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
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ZIV5-80-7-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-80-8-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-80-8-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-80-8-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
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ZIV5-80-8-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-80-9-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-80-9-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
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ZIV5-80-10-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-80-10-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-80-10-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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ZIV5-80-10-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-125-4-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
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ZIV5-125-7-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-125-7-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-125-7-6.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-125-7-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-125-8-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-125-8-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
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ZIV5-125-8-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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ZIV5-125-9-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-125-9-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV5-125-9-6.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
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ZIV5-125-10-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
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ZIV6-80-5-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-80-5-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-80-5-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
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ZIV6-80-7-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
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ZIV6-80-8-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-80-9-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
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ZIV6-80-10-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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ZIV6-80-10-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-80-10-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-80-10-6.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-80-10-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-80-12-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-80-12-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-80-12-6.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-80-12-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-80-14-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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ZIV6-80-14-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-125-5-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-125-5-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
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ZIV6-125-9-2.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
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ZIV6-125-12-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-125-14-3.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-125-14-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-125-14-6.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIV6-125-14-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-10-11-4-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-10-11-6-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-10-11-8-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-8-9-6-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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EVO-FC-8-9-8-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-PC-10-11-4-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-PC-10-11-6-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-PC-10-11-8-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-PC-8-9-6-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-PC-8-9-8-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
RMS-060012-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
RMS-060014-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
RMS-060016-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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RMS-060018-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
RMS-060020-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
RMS-060022-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
RMS-060024-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
RMS-060026-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
RMS-060028-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
RMS-060030-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-20-25-10-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-20-25-12.5-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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EVO-20-25-15-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-20-25-8-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-18-23-10-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-18-23-12-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-18-23-8-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-20-25-10-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-20-25-12-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-20-25-8-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-6-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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ZIB6-40-6-6.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-6-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-8-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-8-6.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-8-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-9-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-9-6.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-9-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-10-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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ZIB6-40-10-6.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-10-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-12-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-12-6.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-12-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-14-4.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-14-6.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZIB6-40-14-8.0	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-22-27-12-D	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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EVO-22-27-6-D	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-22-27-9-D	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-10-10	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-10-12	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-10-4	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-10-6	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-10-8	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-6-10	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-6-12	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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ZILBS-635-6-4	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-6-6	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-6-8	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-8-10	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-8-12	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-8-4	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-8-6	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
ZILBS-635-8-8	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-25-30-10-C	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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EVO-25-30-6-C	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-25-30-8-C	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-R-18-23-10-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-R-18-23-12-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-R-18-23-8-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-R-20-25-10-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-R-20-25-12-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
EVO-FC-R-20-25-8-E	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-500	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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UFI-500-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-500-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-500-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-500-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-522	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-522-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-522-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-524	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-524-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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UFI-524-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-526	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-526-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-526-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-528	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-528-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-528-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-530	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-600	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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UFI-600-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-600-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-600-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-600-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-622	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-622-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-622-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-622-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-624	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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UFI-624-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-624-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-624-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-626	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-626-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-626-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-626-P	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-626-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-626-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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UFI-628	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-628-P	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-628-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-628-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-630	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-700	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-700-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-700-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-700-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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UFI-700-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-722	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-722-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-722-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-724	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-724-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-724-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-724-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-726	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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UFI-726-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-726-P	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-726-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-726-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-728	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-728-P	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-728-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-728-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-822	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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UFI-822-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-824	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-824-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-826	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-826-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-828	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
UFI-828-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-500	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-500-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-500-B-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-500-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-500-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-500-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-512	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-512-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-512-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-512-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-514	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-514-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-516	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-516-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-518	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-520	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-520-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-520-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-520-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-520-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-522	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-522-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-522-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-522-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-522-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-522-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-524	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-524-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-524-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-524-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-524-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-524-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-526	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-526-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-526-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-526-CE-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-526-CE-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-526-CE-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-526-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-526-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-526-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-526-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-528	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-528-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-528-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-528-CE-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-528-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-528-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-528-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-530	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-530-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-530-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-530-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-530-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-600	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-600-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-600-B-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-600-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-600-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-600-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-600-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-600-RPC-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-600-R-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-600-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-612	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-614	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-614-RPC-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-616	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-616-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-618	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-620	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-620-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-620-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-620-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-620-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-622	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-622-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-622-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-622-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-622-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-622-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-622-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-624	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-624-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-624-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-624-CE-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-624-CE-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-624-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-624-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-624-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-624-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-624-RPC-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-624-R-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-624-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-626	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-626-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-626-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-626-CE-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-626-CE-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-626-CE-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-626-CE-RPC-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-626-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-626-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-626-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-626-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-626-RPC-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-626-R-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-626-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-628	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-628-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-628-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-628-CE-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-628-CE-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-628-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-628-LP-PD	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-628-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-628-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-628-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-628-RPC-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-628-R-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-628-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-630	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-630-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-630-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-630-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-630-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-700	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-700-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-700-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-700-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-700-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-700-RPC-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-700-R-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-712	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-714	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-716	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-716-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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Identification of the device(s) <sup>1</sup> (e.g., device name, family/group name, device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period	Substitute Device(s) (if applicable)
USI-718	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-718-P	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-720	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-720-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-720-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-720-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-720-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-722	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-722-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-722-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-722-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-722-P	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-722-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-722-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-724	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-724-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-724-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-724-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-724-P	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-724-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-724-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-724-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-724-RPC-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-724-R-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-726	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-726-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-726-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-726-CE-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-726-CE-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-726-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-726-P	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-726-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-726-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-726-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-726-RPC-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-726-R-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-728	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-728-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-728-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-728-CE-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-728-CE-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-728-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-728-LP-PD	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-728-P	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-728-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-728-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-728-RPC-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-728-RPC-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-728-R-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-728-T	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-730	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-730-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-730-LP	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-730-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-730-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-800	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-800-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-800-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-800-R-P	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-800-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-822	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-822-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-822-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-822-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-824	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-824-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-824-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-824-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-824-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-826	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-826-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-826-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-826-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-826-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-828	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-828-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-828-CE	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-828-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-828-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-830	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-830-B	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A



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USI-830-R	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A
USI-830-RPC	G1 033038 0037 REV 00	26 May 2024	TÜV SÜD Product Service GmbH 0123	TÜV SÜD Product Service GmbH 0123	31 December 2027	N/A

# Final\_MDR\_Manufacturer Declaration (002) IIb implants

Final Audit Report

2024-02-26

Created:	2024-02-26
By:	Saoirse Vaughan (saoirse.vaughan@cookmedical.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAIV53X0W4Ald6xx5boNCbp0xon5QFvc5N

## "Final\_MDR\_Manufacturer Declaration (002) IIb implants" History

-  Document created by Saoirse Vaughan (saoirse.vaughan@cookmedical.com)  
2024-02-26 - 7:53:29 AM GMT
-  Document emailed to Sinead Egan (Sinead.Egan@CookMedical.com) for signature  
2024-02-26 - 7:54:39 AM GMT
-  Email viewed by Sinead Egan (Sinead.Egan@CookMedical.com)  
2024-02-26 - 9:18:30 AM GMT
-  Sinead Egan (Sinead.Egan@CookMedical.com) authenticated with Adobe Acrobat Sign.  
Challenge: The user opened the agreement.  
2024-02-26 - 9:20:03 AM GMT
-  Sinead Egan (Sinead.Egan@CookMedical.com) has agreed to the terms of use and to do business electronically with Cook Incorporated  
2024-02-26 - 9:22:06 AM GMT
-  Document e-signed by Sinead Egan (Sinead.Egan@CookMedical.com)  
Signature Date: 2024-02-26 - 9:22:06 AM GMT - Time Source: server
-  Agreement completed.  
2024-02-26 - 9:22:06 AM GMT

# EC CERTIFICATE

## for the Quality Assurance System



### according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company  
**Electroplast S.A.**

Servando Gómez 2450, 12100 Montevideo, Uruguay

**Certified location:**

Servando Gómez 2450, 12100 Montevideo, Uruguay

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50279-Z6-00, the decision dated 2019-01-22 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-02-25 to 2024-02-24

Registration No.: 50279-16-06

  
Ruth Delbeck-Bayer  
DEKRA Certification GmbH Stuttgart; 2019-01-22  
Notified Body ID-number: 0124

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
**ZLG-BS-295.10.02**

# Annex to the EC Certificate No. 50279-16-06

Valid from 2019-02-25 to 2024-02-24

Revision status of the annex: 0 dated 2019-02-25

Devices/device categories included in the certificate:

## Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- MD 0101 + MDS 7006
  - Urology devices
    - Cistometry catheter
    - Stone extractor
  - Anesthesia devices
    - Accessories for Bronchial Double lumen tube like different connectors

## Class II a:

- MD 0101 + MDS 7006
  - Urology devices
    - Ureter catheter
    - Foleyplast catheter
  - Endo-Urology devices
    - Nephrostomy Set/Catheter
  - Anesthesia devices
    - Tracheal tubes
    - Bronchial Double lumen tube
  - Digestive devices
    - Stomach and oesophageal tubes
    - Rectal tube
  - Surgical devices
    - Embolectomy catheter

## Class II b:

- MD 0101 + MDS 7006
  - Anesthesia devices
    - Tracheostomy tube
- MD 0203 + MDS 7006
  - Urology devices
    - Ureter stent

DEKRA-Bayer

DEKRA Certification GmbH, Stuttgart, 2019-01-22

Notified Body ID-number: 0124

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)

# CE SERTIFIKATAS

Kokybės užtikrinimo sistemai

## Pagal 93/42/EEC Direktyvos II Priedą, išskyrus 4 dalį

DEKRA Certification GmbH, Europos sąjungos notifikuotas organas, patvirtina, kad įmonė

### **Electroplast S.A.**

Servando Gomez 2450, 12100 Montevidėjus, Urugvajus

**Sertifikuojama vieta:**

Servando Gomez 2450, 12100 Montevidėjus, Urugvajus

pritaiko kokybės užtikrinimo sistemą medicinos priemonėms, išvardytoms priede, pagal 93/42/EEC Direktyvos II Priedą. Tai patvirtinama, remiantis pakartotinio sertifikavimo audito rezultatų ataskaita Nr. 50279-Z6-00. Sprendimas, priimtas 2019-01-22, galioja tik sėkmingai atlikus kasmetinius auditus.

Šis sertifikatas galioja nuo 2019-02-25 iki 2024-02-24.

Sertifikato registracijos Nr.: 50279-16-06

/Parašas/ \_\_\_\_\_

DEKRA Certification GmbH

Stuttgart, 2019-01-22

Notifikuoto organo identifikacijos Nr.: 0124

/Rekvizitai/

Priedas prie CE sertifikato Nr. 50279-16-06

Galioja nuo 2019-02-25 iki 2024-02-24

Peržiūros statusas: 0 data 2019-02-25

Įranga/įrangos kategorijos, kurias apima šis priedas:

#### Klasė 1 s:

Žemiau išvardintiems produktams Kokybės užtikrinimo sistemos peržiūra išskirtinai remiasi gamybos aspektais, susijusiais su apsauga ir sterilumo sąlygomis.

- MD 0101 + MDS 7006
  - Urologijos priemonės
    - Cistometrijos kateteriai
    - Akmenų ištraukėjai
  - Anestezijos priemonės
    - Bronchų dviejų spindžių vamzdelių priedai su skirtingais sujungėjais

#### II a Klasė:

- MD 0101 + MDS 7006
  - Urologinės priemonės
    - Ureteriniai kateteriai
    - Foley kateteriai
  - Endo-urologinės priemonės
    - Nefrostomijos rinkiniai/kateteriai
  - Anestezijos priemonės
    - Trachėjiniai vamzdeliai
    - Bronchų dviejų spindžių vamzdeliai
  - Virškinimo priemonės
    - Skrandžio ir stemplės vamzdeliai (Blekmoro zondai)
    - Rektaliniai vamzdeliai
  - Chirurginės priemonės
    - Embolektomijos kateteriai

#### II b klasė:

- MD 0101 +MDS 7006
  - Anestezijos priemonės
    - Tracheostomijos vamzdeliai
- MD 0203 + MDS 7006
  - Urologinės priemonės
    - Ureteriniai stentai

Parašas

Ruth Delbeck Bayer

DEKRA Certification GmbH, Stuttgart, 2019-01-22

DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

Electroplast S.A.  
Mr. Jorge González  
Servando Gómez 2450  
12100 Montevideo  
Uruguay

**DEKRA Certification GmbH**

Handwerkstraße 15  
D-70565 Stuttgart

Contact Karin Leicht  
Phone +49.40.23603-877  
Email karin.leicht@dekra.com

Date 2024-09-26

**Subject: Notified Body Confirmation Letter**

**Our reference: 50279-CoL-01 Rev. 1**

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

Dear Mr. González,

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 on NANDO, hereby confirms that a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR has been lodged and a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer is still pending:

Electroplast S.A.  
Servando Gómez 2450  
12100 Montevideo  
Uruguay

SRN Number (if available): DE-AR-000005702 (EU Representative SRN)

Table 1 identifies the devices for which a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR has been concluded between Electroplast S.A. and DEKRA Certification GmbH and for which DEKRA Certification GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive MDD.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The confirmation letter 50279-CoL-00 Rev. 1 is invalid with immediate effect.

**Validity of this confirmation letter:**

For products included in table 1:

Until the end of applicable transition timelines specified in Article 120.3c of MDR (as amended by (EU) 2023/607

On behalf of the Notified Body,

Enclosures:

Confirmation Letter Annex

## Annex to Notified Body Confirmation Letter 50279-CoL-01 Rev. 1

**Table 1**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification	Agreement for Conformity Assessment
<b>Ureter Catheter</b>	Class IIa	N/A	EC Certificate Registration Number N° 50279-16-06; DEKRA Certification GmbH	50279-CA-00
<b>Foleyplast Catheter</b>	Class IIa	N/A	EC Certificate Registration Number N° 50279-16-06; DEKRA Certification GmbH	50279-CA-00
<b>Nephrostomy Set/Catheter</b>	Class IIa	N/A	EC Certificate Registration Number N° 50279-16-06; DEKRA Certification GmbH	50279-CA-00
<b>Tracheal Tubes</b>	Class IIa	N/A	EC Certificate Registration Number N° 50279-16-06; DEKRA Certification GmbH	50279-CA-00
<b>Bronchial Double Lumen Tube</b>	Class IIa	N/A	EC Certificate Registration Number N° 50279-16-06; DEKRA Certification GmbH	50279-CA-00
<b>Stomach and oesophageal tubes</b>	Class IIa	N/A	EC Certificate Registration Number N° 50279-16-06; DEKRA Certification GmbH	50279-CA-00
<b>Rectal Tube</b>	Class IIa	N/A	EC Certificate Registration Number N° 50279-16-06;	50279-CA-00

			DEKRA Certification GmbH	
<b>Embolectomy Catheter</b>	Class IIa	N/A	EC Certificate Registration Number N° 50279-16-06; DEKRA Certification GmbH	50279-CA-00
<b>Tracheostomy Cannula</b>	Class IIb excluding Class IIb implantable non-WET	N/A	EC Certificate Registration Number N° 50279-16-06; DEKRA Certification GmbH	50279-CA-00
<b>Ureter Stent</b>	Class IIb excluding Class IIb implantable non-WET	N/A	EC Certificate Registration Number N° 50279-16-06; DEKRA Certification GmbH	50279-CA-00

## EU Declaration of Conformity – OptraGate

<b>Product(s)</b>	OptraGate
<b>Document-ID</b>	LL3446299
<b>Document Version</b>	1.0

Document Control		
Name	Date	Signature
<b>Author</b> (Project Manager, RSR): Annina Remm	2020-04-02	<i>Sign. A. Remm</i>
<b>Reviewer</b> (Research Associate, RSC): Patrizia Hoch	2020-04-02	<i>Sign. P. Hoch</i>
<b>Approver</b> (PRRC): Patrik Oehri	2020-04-02	<i>Sign. P. Oehri</i>
<b>Approver</b> (CTO): Dr. Thomas Hirt	2020-04-02	<i>Sign. T. Hirt</i>

Revision History			
Version	Date	Author	Remark
01	2020-04-02	Annina Remm	First MDR Version

## EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

We hereby declare that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer and the below mentioned products meet the provisions of the EU Regulation above. All supporting documentation is retained on the premises of the manufacturer and the Notified Body.

<b>Legal Manufacturer information</b>	<b>Ivoclar Vivadent AG</b> Bendererstrasse 2 9494 Schaan Liechtenstein	Phone +423 / 235 35 35 Fax +423 / 235 33 60 www.ivoclarvivadent.com Legal Form: Joint Stock Company Corporate Headquarters: 9494 Schaan Registration No.: FL-0001.001.595-7 VAT No.: 50639
<b>SRN</b>	not yet available	
<b>Basic UDI-DI</b>	DIVO1xDams001	
<b>Product</b>	<b>OptraGate</b>	
<b>Category (NBOG F 2017-3)</b>	MDA Code: <input type="checkbox"/> MDA 0311 Active non-implantable dental devices <input type="checkbox"/> MDA 0315 Software	
	MDN Code: <input type="checkbox"/> MDN 1103 Non-active dental implants and dental materials <input checked="" type="checkbox"/> MDN 1208 Non-active non-implantable instruments <input type="checkbox"/> MDN 1209 Non-active non-implantable dental materials <input type="checkbox"/> MDN 1214 General non-active non-implantable devices used in health care and non-active non-implantable devices	
<b>EMDN Code + term</b>	Dental devices – various: <input checked="" type="checkbox"/> Q019002 Dental devices, rubber dam and hooks	
<b>EU Risk Classification (MDR Annex VIII)</b>	<input checked="" type="checkbox"/> Medical Device Class I <b>CE</b> <input type="checkbox"/> Medical Device Class IIa <b>CE 0123</b> <input type="checkbox"/> Medical Device Class IIb <b>CE 0123</b> <input type="checkbox"/> Medical Device Class III <b>CE 0123</b>	
<b>Conformity Assessment Procedure (MDR Annex IX)</b>	<input checked="" type="checkbox"/> Quality Management System <input type="checkbox"/> Assessment of the Technical Documentation	
<b>Notified Body Address</b>	<b>TÜV SÜD Product Service GmbH</b> Ridlerstrasse 65 80339 München Deutschland	
<b>EC Certificate No.</b>	<input type="checkbox"/> not yet available <input checked="" type="checkbox"/> N/A	
<b>Place and date of issue</b>	Schaan, 2020-04-02	
<b>Valid until</b>	2025-03-31	

## EC Atitikties Deklaracija – OptraGate

Produktas OptraGate  
Dokumento ID LL3446299  
Dokumento versija 1.0

### Revizija

2020-04-02 Atsakingas asmuo: Annina Remm Pastaba: Pirmoji MDR Versija

### EC Atitikties Deklaracija Pagal Medicinos Prietaisų Reglamentą MDR 2017/745 IV Priedą

Mes pareiškiame, kad ši EC Atitikties Deklaracija yra išduota su gamintojo atsakomybe, o aukščiau išvardinti gaminiai atitinka anksčiau pateikto EC reglamento nuostatas. Visi patvirtinamieji dokumentai saugomi gamintojo ir Notifikuotosios įstaigos patalpose.

Template ID: TEFO-03750-EN Version:2.0, Valid as of: 16 Mar 2020 14:04:53 (GMT+01:00)  
Template title: EU Declaration of Conformity (MDR)  
Module: Product Conformity (MDR)  
Module owner: Head of Department Scientific Service



Gamintojo informacija	Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan Lichtenšteinas
Produktas	OptraGate
Kategorija	MDN 1208 Neaktyvūs Neimplantuojami instrumentai
EMDN Kodas + terminas	Įvairūs odontologiniai prietaisai: Q019002 Odontologiniai prietaisai, koferdamo guma ir kabliukai
EC Rizikos Klasifikacija (MDR VIII Priedas)	Medicininiai Prietaisai Klasė I, CE
Atitikties Vertinimo Procedūra (MDR IX Priedas)	Kokybės Valdymo Sistema
Notifikuotosios Įstaigos adresas	TUV SUD Product Service GmbH Ridlerstrasse 65 80339 Munchen Vokietija
CE Sertifikatas	N/A
Išleidimo vieta ir data	Schaan, 2020-04-02
Galioja iki	2025-03-31



**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60142092 0001

**Report No.:** 15095988 008

**Manufacturer:** Jiangsu BANA Medical Technology  
Co., Ltd.  
No. 28-3 Guihua Road  
Zhonglou Economic Development Zone  
Changzhou  
213013 Jiangsu  
P.R. China

**Products:** Medical Devices  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: HD 60138384 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2020-11-21

Notified Body

**Date:** 2020-11-21



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60142092 0001  
**Report No.:** 15095988 008

**Manufacturer:** Jiangsu BANA Medical Technology  
Co., Ltd.  
No. 28-3 Guihua Road  
Zhonglou Economic Development Zone  
Changzhou  
213013 Jiangsu  
P.R. China

**Products:**

- Hernia Patches
- Disposable Prepuce Cutter Staplers
- Hernia Staplers
- Disposable Endoscopic Ligating Loops
- Disposable Endoscopic Graspers
- Disposable Endoscopic Scissors
- Disposable Endoscopic Dissectors
- Disposable Suction and Irrigation Tubes
- Biopsy Forceps
- Disposable Endoscopic Retrieval Bags
- Disposable Trocars
- Disposable Clip Appliers
- Disposable Veress Needles
- Non-sterile Metallic Bone Plates
- Non-sterile Metallic Bone Screws
- Spinal Internal Fixation
- Non-sterile Metallic Intramedullary Femur Nails
- Non-sterile Metallic Intramedullary Tibia Nails
- Non-sterile Metallic Intramedullary Humerus Nails

**Notified Body**

**Date:** 2020-11-21

**Fuxiu Sheng**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60142092 0001  
**Report No.:** 15095988 008

**Manufacturer:** Jiangsu BANA Medical Technology  
Co., Ltd.  
No. 28-3 Guihua Road  
Zhonglou Economic Development Zone  
Changzhou  
213013 Jiangsu  
P.R. China

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

- Dilators

**Notified Body**



**Date:** 2020-11-21

**ruxiu sneng**

## EC Sertifikatas

Direktyvos 93/42/EEC Priedas Nr. II, išskyrus 4 skirsnį

KOKYBĖS UŽTIKRINIMO SISTEMA

Medicinos prietaisai

Registracijos Nr.: HD 60142092 0001

Ataskaitos Nr.: 15095988 008

**Gamintojas:** Jiangsu BANA Medical Technology  
CO., LTD.  
No. 28-3 Guihua Road  
Zhonglou Economic Development Zone  
Changzhou  
213013 Jiangsu  
P.R. Kinija

**Produktai:** Medicinos prietaisai (žiūrėti pridėtame produktų priede)

**Galioja iki:** 2024-05-26

Notifikuojančioji įstaiga patvirtina, kad toliau išvardinti produktai atitinka direktyvos 93/42/EEC II Priedą, išskyrus 5 skirsnį. Aukščiau minimas gamintojas įtvirtino ir vykdo kokybės užtikrinimo sistemą, taip pat periodinę priežiūrą, patvirtintą minimos direktyvos II Priedo 5 skirsnyje. Pateikimas į rinką produktų, kuriems taikomas šis sertifikatas ir EB pakuotės dizaino atitikimo sertifikatas pagal II Priedo 4 skirsnį, yra galimas.

**Įsigaliojimo Data:** 2020-11-21

**Data:** 2020-11-21



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Priedas prie Sertifikato**

**Registracijos Nr.: HD 60142092 0001**

**Ataskaitos Nr.: 15095988 008**

**Gamintojas: Jiangsu BANA Medical Technology  
CO., LTD.  
No. 28-3 Guihua Road  
Zhonglou Economic Development Zone  
Changzhou  
213013 Jiangsu  
P.R. Kinija**

Produktai:

- Išvaržos Tinklai;
- Vienkartiniai Stapleriai;
- Išvaržų Stapleriai;
- Vienkartinės Endoskopinės Ligavimo Kilpos;
- Vienkartiniai Endoskopiniai Žnyplės;
- Vienkartinės Endoskopinės Žirklys;
- Vienkartiniai Endoskopiniai Disektoriai;
- Vienkartiniai Siurbimo / Irigavimo Vamzdeliai;
- Biopsinės Žnyplės;
- Vienkartiniai Endoskopiniai Organų/Audinių Ištraukimo Maišeliai;
- Vienkartiniai Trokarai;
- Vienkartiniai Kabučių Aplikatoriai;
- Vienkartinės Veress Adatos;
- Nesterilūs Metaliniai Kaulų Implantai;
- Nesterilūs Metaliniai Kaulų Sraigčiai;
- Vidiniai Stuburo Fiksatoriai;
- Nesterilios Metalinės Intramedulinės Šlaunikaulio Vinys;
- Nesterilios Metalinės Intramedulinės Blauzdikaulio Vinys;
- Nesterilios Metalinės Intramedulinės Žąstikaulio Vinys.

**Data: 2020-11-21**



**TÜV Rheinland**  
**LGA Products GmbH**  
Tillystraße 2, 90431 Nürnberg

**Priedas prie Sertifikato**

**Registracijos Nr.: HD 60142092 0001**

**Ataskaitos Nr.: 15095988 008**

**Gamintojas: Jiangsu BANA Medical Technology**  
**CO., LTD.**  
**No. 28-3 Guihua Road**  
**Zhonglou Economic Development Zone**  
**Changzhou**  
**213013 Jiangsu**  
**P.R. Kinija**

Gamybos aspektai, susiję su sterilių sąlygų užtikrinimu ir palaikymu:

- Dilatoriai.

**Date: 2020-11-21**



TÜV Rheinland LGA Products GmbH • 51105 Köln

Jiangsu BANA Medical Technology Co., Ltd.  
No.28-3, Guihua Road, Zhonglou Economic Development Zone,  
Changzhou,  
213013 Jiangsu  
P.R. China

Contact

Tel. +49 911 655-5225  
Mail: [medical-products@de.tuv.com](mailto:medical-products@de.tuv.com)

Date May 22, 2024

### **Notified Body Confirmation Letter**

Reference. : 326008266

To whom it may concern,

### **Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.**

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Jiangsu BANA Medical Technology Co., Ltd.  
No.28-3, Guihua Road, Zhonglou Economic Development Zone,  
Changzhou, 213013 Jiangsu  
P.R. China  
SRN Number: CN-MF-000025963

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland  
LGA Products GmbH

Am Grauen Stein  
51105 Köln  
Germany

Headquarter

Tillystraße 2  
90431 Nuremberg

Phone. +49 911 655 5225  
Fax +49 911 655 5226  
service@de.tuv.com  
[www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Nuremberg HRB 26013  
VAT No.: DE 811835490

Chairman of the  
Supervisory Board

Dr.-Ing. Michael Fübi

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notifi

[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Disposable Endoscopic Retrieval Bags  Models:QW2  Basic UDI-DI: 69411733QW22H	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Retrieval Bags  Models:QW4  Basic UDI-DI: 69411733QW42M	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Retrieval Bags  Models:QW5  Basic UDI-DI: 69411733QW52P	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Retrieval Bags  Models:QW7  Basic UDI-DI: 69411733QW72T	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Retrieval Bags  Models:QW8  Basic UDI-DI: 69411733QW82V	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
Disposable Suction and Irrigation Tubes  Models: CX330-II, CX430-II  Basic UDI-DI: 69411733CXIISP	Class IIa	Disposable Suction and Irrigation Tubes  Models: CX330, CX430	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Suction and Irrigation Tubes  Models: CX330-III, CX430-III  Basic UDI-DI: 69411733CXIIIPV	Class IIa	Disposable Suction and Irrigation Tubes  Models: CX330, CX430	Certificate #: HD 60142092 0001 NB #: 0197
Hernia Staplers  Models: LW-350, LW-110  Basic UDI-DI: 69411733LWEA	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Dilators  Models: 5,7,9,11,13,15  Basic UDI-DI: 69411733KZED	Class I devices placed on the market in sterile condition	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Trocars  Models: CCQ-W  Basic UDI-DI: 69411733CCQWR2	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Trocars  Models: CCQ-Y  Basic UDI-DI: 69411733CCQYR6	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
Disposable Trocars  Models: CCQ-G  Basic UDI-DI: 69411733CCQGQ2	Class IIa	Disposable Trocars  Models: CCQ-W	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Veress Needles  Models: QF-120, QF-150  Basic UDI-DI: 69411733QFDP	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Ligating Loops  Models: TZ-300  Basic UDI-DI: 69411733TZF8	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Hernia Patches  Models: SB-A  Basic UDI-DI: 69411733SBAZM	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Hernia Patches  Models: SB-B  Basic UDI-DI: 69411733SBBZP	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Hernia Patches  Models: SB-C  Basic UDI-DI: 69411733SBCZR	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Prepuce Cutter Staplers  Models: NBWA  Basic UDI-DI: 69411733NBWASG	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Disposable Prepuce Cutter Staplers  Models: NBWB  Basic UDI-DI: 69411733NBWBSJ	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Prepuce Cutter Staplers  Models: NBWC  Basic UDI-DI: 69411733NBWCSL	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Graspers  Models: ZQ330、ZQ430  Basic UDI-DI: 69411733ZQF8	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Scissors  Models: JD330、JD430  Basic UDI-DI: 69411733JDCW	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Disposable Endoscopic Dissectors  Models: FQ330、FQ430  Basic UDI-DI: 69411733FQDC	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197
Biopsy Forceps  Models: HQ1.8、HQ2.3  Basic UDI-DI: 69411733HQDJ	Class IIa	N/A	Certificate #: HD 60142092 0001 NB #: 0197

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
None			

**Confirmation Letter Revision History**

<b>Date</b>	<b>NB internal reference traceable to each version of the letter</b>	<b>Action</b>
2024-5-22	326008266	Initial issue

## Sertifikavimo Deaprtamentas

TÜV Rheinland LGA Products GmbH • 51105 Köln  
Jiangsu BANA Medical Technology Co., Ltd.  
No.28-3, Guihua Road, Zhonglou Economic Development Zone,  
Changzhou,  
213013 Jiangsu  
P.R. China

Contact  
Tel. +49 911 655-5225  
Mail: [medical.products@de.tuv.com](mailto:medical.products@de.tuv.com)  
Date May 22, 2024

### Notifikuotosios Įstaigos Patvirtinimo Laiškas

Nuoroda: 326008266

Tiems, kam tai gali būti aktualu

**Oficialaus prašymo statuso patvirtinimas, rašytinis susitarimas ir tinkamą priežiūrą pagal Reglamentą ES 2023/607 iš dalies keičiantys reglamentus (ES) 2017/745 ir (ES) 2017/746 dėl pereinamojo laikotarpio nuostatos tam tikriems medicinos prietaisams ir in vitro diagnostikai Medicininiai prietaisai.**

Šis laiškas patvirtina, kad notifikuotoji įstaiga **TÜV Rheinland LGA Products GmbH** (NB), priskirtas pagal Reglamentą (ES) 2017/745 (MDR) ir nurodytas pagal **0197 NANDO**, gavo oficialų prašymą pagal MDR VII priedo 4.3 skirsnio pirmą pastraipą ir pasirašė rašytinį dokumentą susitarimą pagal VII priedo 4.3 skirsnio antrąją pastraipą MDR su šiuo gamintoju:

Jiangsu BANA Medical Technology Co., Ltd.  
Nr.28-3, Guihua Road, Zhonglou ekonominės plėtros zona,  
Changzhou, 213013 Jiangsu  
P.R. Kinija  
SRN numeris: CN-MF-000025963

Įrenginiai, kuriems pateikta oficiali paraiška ir nurodytas rašytinis susitarimas nurodyti toliau pateiktose lentelėse. 1 lentelėje nurodyti įrenginiai, kuriems gautas MDR prašymas, sudaryta rašytinė sutartis ir dėl kurios NB taip pat yra atsakinga už tinkamą priežiūrą pagal taikomą direktyvą. 2 lentelėje nurodyti įrenginiai, kuriems buvo gauta MDR programa ir sudaryta rašytinė sutartis, tačiau NB atsakomybės dar neprisiėmė tinkamai prižiūrėti atitinkamus įrenginius pagal taikomus reikalavimus direktyvą.

Prietaisams, kuriems išduoti sertifikatai pagal Direktyvą 90/385/EEB (AIMDD) arba Direktyva 93/42/EEB (MDD), kuri nustojo galioti po 2021 m. gegužės 26 d., bet anksčiau 2023

m. kovo 20 d. nebuvo atšaukta, šis raštas taip pat patvirtina, kad gamintojas arba pasirašė rašytinį susitarimą pagal MDR iki datos MDD/AIMDD (sertifikato galiojimo laikas); arba pateikė įrodymų, kad kompetentinga institucija valstybė narė buvo suteikusi leidžiančią nukrypti nuostatą arba atleisti nuo taikytinos atitikties vertinimo procedūros pagal MDR 59 straipsnio 1 dalį arba 97 straipsnio 1 dalį MDR atitinkamai iki 2023 m. kovo 20 d. atitinkamiems įrenginiams.

Pereinamojo laikotarpio terminai, taikomi įrenginiams, kuriems taikomas šis raštas, atsižvelgiant į tai, kad gamintojas nuolat laikosi kitų straipsnyje nurodytų sąlygų MDR 120.3c (su pakeitimais, padarytais (ES) 2023/607), pateikiami toliau:

- 2026 m. gegužės 26 d. III klasės pagal užsakymą gaminamiems implantuojamiems prietaisams
- 2027 m. gruodžio 31 d. III klasės prietaisams ir IIb klasės implantuojamiems prietaisams. Išskyrus nusistovėjusias technologijas (WET - siūlai, kabės, odontologijos plombos, dantų breketai, dantų vainikėliai, varžtai, pleištai, plokštelės, laidai, kaiščiai, spaustukai ir jungtys)
- 2028 m. gruodžio 31 d. kitiems IIb klasės, IIa klasės, I klasės įrenginiams pateikiami į rinką sterilūs arba turintys matavimo funkciją
- 2028 m. gruodžio 31 d. įrenginiams, kuriems netaikomi MDD reikalavimai, bet reikalingi pagal MDR (pvz., I klasės įrenginiai, kurie kvalifikuojami kaip pakartotinai naudojami chirurginiai instrumentai)

Notifikuotosios Įstaigos  
Už Sertifikavimą atsakingas asmuo  
Herbert Zhong

*parašas*



Reg. Numero / Reg. Number	MED 26032	Revisione / Revision	10
Primo rilascio / First issue date	2006-09-07	Valido da / Valid from	2021-05-24
Scadenza / Valid until	2024-05-26	Ultima modifica / Last change date	2021-05-24

Pagina / Page 1 di / of 4

## Certificato CE del Sistema di Garanzia della Qualità *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

### LUMED S.r.l.

**Sede Operativa / Operational Headquarter:**

Via Staffora, 18/9  
20073 Opera, MI - Italia

**Sede legale / Registered Headquarter**

Via Vittor Pisani, 28  
20124 Milano, MI - Italia

**Sede Operativa / Operational Headquarter**

Via Senio, 36/40  
47121 Forlì, FC - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Carte di registrazione per apparecchiature elettromedicali / *Recording chart paper for medical devices*

Dispositivi monouso per diagnostica polmonare / *Disposable devices for pulmonary test*

Elettrocardiografi / *Electrocardiographs*

Elettrocardiografi di seconda generazione / *Electrocardiographs*

Holter ECG / *Holter systems*

Kiwa Cermet Italia S.p.A.  
Società con socio unico, soggetta  
all'attività di direzione e coordinamento  
di Kiwa Italia Holding S.r.l.  
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40057 Granarolo dell'Emilia (BO)  
Tel +39.051.459.3.111  
Fax +39.051.763.382  
E-mail: info@kiwacermet.it  
www.kiwacermet.it

Rif. rapporto

3-14-15/01/2021

Firmato digitalmente da:BELCREDI GIAMPIERO  
Data:24/05/2021 17:06:11



Organismo Notificato n. 0476  
Notified Body nr. 0476



Reg. Numero / Reg. Number	MED 26032	Revisione / Revision	10
Primo rilascio / First issue date	2006-09-07	Valido da / Valid from	2021-05-24
Scadenza / Valid until	2024-05-26	Ultima modifica / Last change date	2021-05-24

## Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

### Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

#### Tipologia / Medical Devices:

Carte di registrazione per apparecchiature elettromedicali / Recording chart paper for medical devices

#### Classe di rischio / Risk class:

I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

#### Codice NANDO / NANDO codes:

MD 0104

#### Modello / Model:

Carte termiche prive di Bisfenoli / Phenol free chart paper

#### Codici / Codes:

CF aa xxx (/yyy) BF aa xxx (/yyy)

#### Tipologia / Medical Devices:

Dispositivi monouso per diagnostica polmonare / Disposable devices for pulmonary test

#### Classe di rischio / Risk class:

II a

#### Codice NANDO / NANDO codes:

MD 0106

#### Modello / Model:

Boccagli / Mouthpieces

#### Codici / Codes:

TSxxxx (/yyyy); 910300

#### Modello / Model:

Boccagli con filtro antiparticolato / Mouthpieces with particulate filter

#### Codici / Codes:

TSFxxxx

#### Modello / Model:

Filtri B.V. (batterici - virali) / Bacterial-viral filters

#### Codici / Codes:

TSVBM xxx (/yyy)

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Firmato dig  
Data:24/05





Reg. Numero / Reg. Number	MED 26032	Revisione / Revision	10
Primo rilascio / First issue date	2006-09-07	Valido da / Valid from	2021-05-24
Scadenza / Valid until	2024-05-26	Ultima modifica / Last change date	2021-05-24

## Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

### Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

**Tipologia / Medical Devices:**  
Elettrocardiografi / *Electrocardiographs*

**Classe di rischio / Risk class:**  
II a

**Codice NANDO / NANDO codes:**  
MD 1302

**Modello / Model:**  
euro\_ecg 3view; euro\_ecg 6view; euro\_ecg 12view;

**Codici / Codes:**  
EP-LU30001 EP-LU30002 EP-LU30003

**Tipologia / Medical Devices:**  
Elettrocardiografi di seconda generazione / *Electrocardiographs*

**Classe di rischio / Risk class:**  
II a

**Codice NANDO / NANDO codes:**  
MD 1302

**Modello / Model:**  
euro\_ecg 301A; euro\_ecg 301; euro\_ecg 301B; euro\_ecg 601A; euro\_ecg 601; euro\_ecg 601B; euro\_ecg 1201A; euro\_ecg 1201; euro\_ecg 1201B

**Codici / Codes:**  
EP-LU30111, EP-LU30101, EP-LU30121, EP-LU30112, EP-LU30102, EP-LU30122, EP-LU30113, EP-LU30103, EP-LU30123

# CERTIFICATE



Reg. Numero / Reg. Number	MED 26032	Revisione / Revision	10
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Scadenza / Valid until	2024-05-26	Ultima modifica / Last change date	2021-05-24

## Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

### Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

**Tipologia / Medical Devices:**  
Holter ECG / Holter systems

**Classe di rischio / Risk class:**  
II a

**Codice NANDO / NANDO codes:**  
MD 1302

**Modello / Model:**  
euro\_holter 3view ; euro\_holter 12view

**Codici / Codes:**  
EP-LU20001 EP-LU20002 EP-LU20003 EP-LU20004

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

# CERTIFICATE

Kiwa Cermet Italia S.p.A.  
Società con socio unico, soggetta  
all'attività di direzione e coordinamento  
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Via Cadriano, 23  
40057 Granarolo dell'Emilia (BO)  
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E-mail: info@kiwacermet.it  
www.kiwacermet.it

Firmato di  
Data:24/0

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Organismo Notificato n. 0476  
Notified Body nr. 0476



Reg. Numeris MED 26032  
Pirmo suteikimo data 2006-09-07  
Galioja iki/ 2024-05-26

Peržiūra/ 10  
Galioja nuo/ 2021-05-24  
Paskutinio pakeitimo data/ 2021-05-24

Puslapis 1 iš 4

## EB kokybės užtikrinimo sistemos

Patvirtiname, kad atliktų auditų pagrindu Organizacijos Gamybos kokybės užtikrinimo sistema:

## LUMED S.r.l.

### Operatyvinė būstinė:

Via Staffora, 18/9  
20073 Opera, MI - Italija

### Registruota būstinė

Via Vittor Pisani, 28  
20124 Milanas, MI - Italija

### Operatyvinė būstinė

Via Senio, 36/40  
47121 Forlì, FC - Italija

Atitinka taikomus 93/42/EEB direktyvos su pakeitimais V priedo reikalavimus, kuriuos Italijoje perkėlė Dlg. 1997/02/24 46 su pakeitimais dėl šių medicinos prietaisų:

Medicinos prietaisų įrašymo diagramų popierius  
Vienkartiniai prietaisai plaučių tyrimui  
Elektrokardiografija  
Elektrokardiografai  
Holter sistemos

Ref. audito ataskaita:

12-13-14-15/01/2021

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G

Firmato d  
Data:24/

Kiwa Cermet Italia S.p.A.  
Società con socio unico, soggetta  
all'attività di direzione e coordinamento  
di Kiwa Italia Holding S.r.l.  
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CERMET



Organismo Notificato n. 0476  
Notified Body nr. 0476



Reg. Numeris MED 26032  
Pirmo suteikimo data 2006-09-07  
Galioja iki 2024-05-26

Peržiūra 10  
Galioja nuo 2021-05-24  
Paskutinio pakeitimo data 2021-05-24

Pslapis 2 iš 4

# CERTIFICATE

## *Prie sertifikato pridedamas techninis lapas*

*Medicinos prietaisų identifikavimas:*

### **Medicinos prietaisas:**

*Medicinos prietaisų įrašymo diagramų popierius*

### **Rizikos klasė:**

tik su metrologiniais reikalavimais susijusiais aspektais

### **NANDO kodas:**

MD 0104

### **Modelis:**

Diagramos popierius be fenolio

### **Kodas:**

CF aa xxx (/yyy) BF aa xxx (/yyy)

### **Medicinos prietaisas:**

*Vienkartiniai prietaisai plaučių tyrimui*

### **Rizikos klasė:**

II a

### **NANDO kodas:**

MD 0106

### **Modelis:**

Kandikliai

### **Kodai:**

TSxxxx (/yyyy); 910300

### **Modelis:**

Kandikliai su kietųjų dalelių filtru

### **Kodai:**

TSFxxxx

### **Modelis:**

Bakteriniai-virusiniai filtrai

### **Kodai:**

TSVBM xxx (/yyy)

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Firmato dig  
Data:24/05

Kiwa Cermet Italia S.p.A.  
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Organismo Notificato n. 0476  
Notified Body nr. 0476



Reg. numeris MED 26032  
Pirmo suteikimo data 2006-09-07  
Galioja iki 2024-05-26

Peržiūra 10  
Galioja iki 2021-05-24  
Paskutinio pakeitimo data 2021-05-24

Puslapis 3 iš 4

CERTIFICATE

*Prie sertifikato pridedamas techninis lapas  
Medicinos prietaisų identifikavimas:*

**Mediciniai prietaisai:**

*Elektrokardiografai*

**Rizikos klasė:**

II a

**NANDO kodas:**

MD 1302

**Modelis:**

euro\_ecg 3view; euro\_ecg 6view; euro\_ecg 12view;

**Kodai:**

EP-LU30001 EP-LU30002 EP-LU30003

**Medicinos prietaisai:**

*Elektrokardiografai*

**Rizikos klasė:**

II a

**NANDO kodas:**

MD 1302

**Modelis:**

euro\_ecg 301A; euro\_ecg 301; euro\_ecg 301B; euro\_ecg 601A; euro\_ecg 601; euro\_ecg 601B; euro\_ecg 1201A; euro\_ecg 1201; euro\_ecg 1201B

**Kodai:**

EP-LU30111, EP-LU30101, EP-LU30121, EP-LU30112, EP-LU30102, EP-LU30122, EP-LU30113, EP-LU30103, EP-LU30123

Kiwa Cermet Italia S.p.A.  
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www.kiwacermet.it

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Data:24/05/



Organismo Notificato n. 0476  
Notified Body nr. 0476



Reg. Numeris MED 26032  
Pirmo suteikimo data 2006-09-07  
Galoja iki 2024-05-26

Peržiūra 10  
Galoja nuo 2021-05-24  
Paskutinio pakeitimo data 2021-05-24

Puslapis 4 iš 4

# CERTIFICATE

## Prie sertifikato pridedamas techninis lapas

Medicinos prietaisų identifikavimas:

**Medicinos prietaisai:**

Holterio sistema

**Rizikos klasė:**

II a

**NANDO kodai:**

MD 1302

**Modelis:**

euro\_holter 3view ; euro\_holter 12view

**Kodas:**

EP-LU20001 EP-LU20002 EP-LU20003 EP-LU20004

Visą kodų, susijusių su sertifikuotais modeliais, sąrašą rasite Kiwa Cermet Italia. Šiam sertifikatui taikomi Kiwa Cermet Italia reglamentai ir jis galioja tik pirmiau minėtiems medicinos prietaisams, kuriems taikomas tyrimas. Techninis lapas yra sudedamoji šio sertifikato dalis.

Kiwa Cermet Italia S.p.A.  
Società con socio unico, soggetta  
all'attività di direzione e coordinamento  
di Kiwa Italia Holding S.r.l.  
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40057 Granarolo dell'Emilia (BO)  
Tel +39.051.459.3.111  
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www.kiwacermet.it

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Gia

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Firmato digital  
Data:24/05/20





May 20<sup>th</sup> , 2024

C/0390/24/GF/mm

To: LUMED S.r.l.  
Via Vittor Pisani, 28  
20124 - Milano, (MI)

Bureau Veritas Italia SpA

**Notified Body Confirmation Letter** with reference to the CE Marking **Certificate n° MED 26032 rev.10 - Directive 93/42/EEC (MDD)**

This letter confirms that, Bureau Veritas Italia SpA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1370 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement n. 5209721 rev.3 in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

LUMED S.r.l.  
Via Vittor Pisani, 28  
20124 - Milano, (MI)  
Italia

Tabella n.1

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>Device name under MDD corresponding to the device under MDR application</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application</b>
BOCCAGLI	Ila	Boccagli / Mouthpieces	Certificate n° MED 26032 rev.10 issued by NB KIWA identified by n. 0476 on 2021/05/24
FILTRI B.V. (Batterici Virali)	Ila	Filtri B.V. (batterici – virali) Bacterial-viral filters	Certificate n° MED 26032 rev.10 issued by NB KIWA identified by n. 0476 on 2021/05/24
Boccaglio con filtro per Spirometria (BOFAP)	Ila	Boccagli con filtro antiparticolato / Mouthpieces with particulate filter	Certificate n° MED 26032 rev.10 issued by NB KIWA identified by n. 0476 on 2021/05/24
Elettrocardiografi di seconda generazione	Ila	Elettrocardiografi di seconda generazione / Electrocardiographs	Certificate n° MED 26032 rev.10 issued by NB KIWA identified by n. 0476 on 2021/05/24
Holter ECG	Ila	Holter ECG / Holter systems	Certificate n° MED 26032 rev.10 issued by NB KIWA identified by n. 0476 on 2021/05/24
Carte di registrazione per apparecchiature	Im	Carte di registrazione per apparecchiature	Certificate n° MED 26032 rev.10 issued by NB KIWA



**BUREAU  
VERITAS**

elettromedicali		elettromedicali / Recording chart paper for medical devices	identified by n. 0476 on 2021/05/24
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In accordance with EU Regulation 2023/607 of the European Parliament of the Council of 15 March 2023, Bureau Veritas Italia hereby confirms that:

- a. The above-mentioned agreement n. 5209721 rev.3 was signed within 2024/09/26.
- b. Bureau Veritas Italia Spa is not responsible for the appropriate surveillance of medical devices certified under Directive 93/42/EEC and subsequent amendments, corresponding to medical devices for which an agreement has been signed for certification according to EU Regulation 2017/745 (MDR) as shown in table n.1

As required by EU Regulation 2023/607, the validity of the MDD certificate n° **MED 26032 rev.10** is extended until 2028/12/31, assuming that the manufacturer continues to comply with all the applicable conditions specified by EU Regulation 2023/607.

### Confirmation Letter Revision History

Date	Revision	Action
2024/05/20	0	Initial issue