Declaration of Conformity

We,

Manufacturer
Integration Diagnostics Sweden AB
Furstenbergsgatan 4
416 64 Göteborg, Sweden
SRN: SE-MF-000018550

declare under our sole responsibility that the Products listed below, and to which this declaration relates, conform to the General Safety and Performance Requirements of the following regulations, directives and to the listed legal requirements, without involvement of notified body:

- Medical Device Regulation (EU) 2017/745
- Directive 2014/53/EU
- Directive 2011/65/EU as amended by (EU) 2015/863
- Directive 2012/19/EU
- Directive 2006/66/EC

Medical device Risk class: I according to Rule 5 in Annex VIII, Medical Device Regulation (EU) 2017/745.

The devices are indicated for use in measuring the stability of dental implants. List of Products (Product Code/ Product Name) as per list on page 2-3. Other information:

- Basic UDI-DI: 735009632PenguinRF
- EMDN: Q0199 Odontology devices - other
- GMDN: 36576 Measuring instrument, universal instrument

We declare that the Conformity Assessment procedure for the listed devices has been conducted in accordance with the requirements specified in Annex IX of the Regulation (EU) 2017/745.

This declaration is supported by the Quality system approval according to ISO 13485 certificate No. 5911 issued by Rise Research Institutes of Sweden AB.

Gothenburg, Mar, 06th , 2024

Name: Martin Hillsten
Function: General Manager

Signature:

Integration Diagnostics Sweden AB
Furstenbergsgatan 4
416 64 Göteborg
Sweden

Integration Diagnostics

Product Code	Product Name	Product Code	Product Name
55002	Penguin RFA Instrument Kit	55033	MulTipeg™ 25
55002-HM	IS3 Instrument Kit	55034	MulTipeg™ 26
55002-S	Penguin RFA Instrument Kit	55035	MulTipeg™ 27
Y1004175	Osseo 100 Set	55036	MulTipeg™ 28
Y1004176	Osseo 100+ Set	55037	MulTipeg™ 29
Y1004176-S	Osseo 100+ Straumann Set	55038	MulTipeg™ 30
55250	Penguin II Set	55039	MulTipeg™ 31
55250-HM	IS4 Instrument Set	55040	MulTipeg™ 32
55250-C	Penguin II Set	55041	MulTipeg™ 33
55250-B	Penguin II Set	55042	MulTipeg™ 34
55250-Nu	Penguin II Set	55043	MulTipeg™ 35
55250-K	Penguin II Set	55044	MulTipeg™ 36
55251	Penguin II DEMO Set	55045	MulTipeg™ 37
55003	MulTipeg Driver	55046	MulTipeg™ 38
55004	MulTipeg™ 18	55047	MulTipeg™ 39
55010	MulTipeg™ 13	55048	MulTipeg™ 40
55011	MulTipeg™ 1	55049	MulTipeg™ 41
55012	MulTipeg™ 2	55050	MulTipeg™ 42
55013	MulTipeg™ 3	55051	MulTipeg™ 43
55014	MulTipeg™ 4	55052	MulTipeg™ 44
55015	MulTipeg™ 5	55053	MulTipeg™ 45
55016	MulTipeg™ 6	55054	MulTipeg™ 46
55017	MulTipeg™ 7	55055	MulTipeg™ 47
55018	MulTipeg™ 8	55056	MulTipeg™ 48
55019	MulTipeg™ 9	55057	MulTipeg™ 49
55020	MulTipeg™ 10	55058	MulTipeg™ 50
55021	MulTipeg™ 11	55059	MulTipeg™ 51
55022	MulTipeg™ 12	55060	MulTipeg™ 52
55023	MulTipeg™ 14	55061	MulTipeg™ 53
55024	MulTipeg™ 15	55062	MulTipeg™ 54
55025	MulTipeg™ 16	55063	MulTipeg™ 55
55026	MulTipeg™ 17	55064	MulTipeg™ 56
55027	MulTipeg™ 19	55065	MulTipeg™ 57
55028	MulTipeg™ 20	55066	MulTipeg™ 58
55029	MulTipeg™ 21	55067	MulTipeg™ 59
55030	MulTipeg™ 22	55068	MulTipeg™ 60
55031	MulTipeg™ 23	55069	MulTipeg™ 61
55032	MulTipeg™ 24	55070	MulTipeg™ 62

Product Code	Product Name	Product Code	Product Name
55071	MulTipeg™ 63	55088	MulTipeg™ 80
55072	MulTipeg™ 64	55115	MulTipeg™ 81
55073	MulTipeg™ 65	55116	MulTipeg™ 82
55074	MulTipeg™ 66	55117	MulTipeg™ 83
55075	MulTipeg™ 67	55118	MulTipeg™ 84
55076	MulTipeg™ 68	55119	MulTipeg™ 85
55077	MulTipeg™ 69	55120	MulTipeg™ 86
55078	MulTipeg™ 70	55121	MulTipeg™ 87
55079	MulTipeg™ 71	55122	MulTipeg™ 88
55080	MulTipeg™ 72	55125	MulTipeg™ 91
55081	MulTipeg™ 73	55126	MulTipeg™ 92
55082	MulTipeg™ 74	55127	MulTipeg™ 93
55083	MulTipeg™ 75	55128	MulTipeg™ 94
55084	MulTipeg™ 76	55129	MulTipeg™ 95
55085	MulTipeg™ 77	55130	MulTipeg™ 96
55086	MulTipeg™ 78	55131	MulTipeg™ 97
55087	MulTipeg™ 79		