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Technical Report

Testing Laboratory
Medical Devices

Report No. 12799411532 dated 13.12.2012

Applicant:	Cattani S.P.A. Via G. Natta 6/A, 43100 Parma, Italy
Device under test:	Amalgam separator "HYDROCYCLONE ISO-60"
Test principles:	DIN EN ISO 11143 : 2008-10 (5.1, 5.2, 5.3, 5.4, 5.5) DIBt – Zulassungsgrundsätzen
Order no.:	8000411532
File no.:	2.4-1135/02
Test engineer:	Jan Hilgers
Testing period:	07.2012
Place of testing:	Langemarckstrasse 20, 45141 Essen, Germany Via G. Natta 6/A, 43100 Parma, Italy

The report consists of 3 pages

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This Technical Report contains the result of the examination of the product sample submitted by the manufacturer. A general statement concerning the quality of the products from the series manufacture cannot be derived therefrom.

1. General

Technical Ratings:

Type according DIN EN ISO 11143 chapter 4: Type 4

Maximum Water flow rate: Q max = 55 l/min

Type of examination: Information test

2. Submitted files

- Technical drawings
- Circuit diagrams

3. Conducted test

- Separation degree Test
- Tests according DIN EN ISO 11143:2008-10 Chapter 5.2 – 5.5

4. Annex

- Testprogram for separation degree Test (2 pages)
- Technical drawings, circuit diagrams (14 pages)
- Photo documentation (1 page)
- Certificate and X-Ray-Sedigramm for Amalgam probes (4 pages)
- Leakage test according DIBt Berlin (2pages)

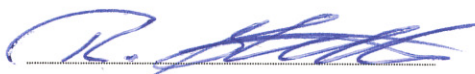
5. Test result

The referencend units are in compliance with the above requirements.

The amalgam separator HYDROCYCLONE ISO-60 has passed the test of the separation degree according DIN EN ISO 11143 : 2008-10 to section 5.1 to 5.6 with amalgam samples according to DIN EN ISO 11143 : 2002-12 section 8, with an efficiency of 98,7%.

The characteristic value for the grade of filling is the high of filling in the collector box.

The test according section 5.2, 5.3 and 5.4 results that the warning and alarm system operate in compliance with the requirements of the standard.



Reviewed: *Reinhard Heller*



Expert: *Jan Hilgers*

Test program Separation degrees EN ISO 11143:2002-12
Dental Equipment-Amalgam Separators

Test Date: 07.2012

Expert: Hlg

Applicant: Cattani SPA
Via Natta, 6/A
43100 Parma
Italy

Test object: hydrocyclone ISO 60
Classification: Type 4: combination system
Minimum Water flow rate: 1 l/min
Maximum water flow rate: 55 l/min

Amalgam sample: Becker Meßtechnik GmbH, 65760 Eschborn, Germany
ISO 11143 Standardprobe
Membrane filters: Satorius AG 11301-142-G (8.0 µ), 11302-142-G (3.0 µ)
11303-142-G (1.2µ)
Balance: Bell UM 205 Ser. No.: 51521

Number of tests performed: 12
Dispersionsmittel: Natriumpyrophosphat

Separation degrees of empty amalgam separator with maximum flow rate:

No.	Separation degrees [%]	Probe No.	Chargen Nr.:
1	98,7 %	17	100416-12/11
2	98,6 %	18	100416-12/11
3	98,6 %	29	100416-12/11

Average: 98,7 %

Separation degrees of full amalgam separator with maximum flow rate:

No.	Separation degrees [%]	Probe No.	Chargen Nr.:
1	98,7 %	34	100416-12/11
2	98,7 %	35	100416-12/11
3	98,7 %	27	100416-12/11

Average: 98,7 %

Separation degrees of empty amalgam separator with minimal flow rate:

Nr.	Separation degrees [%]	Proben Nr.	Chargen Nr.:
1	98,9 %	30	100416-12/11
2	98,9 %	32	100416-12/11
3	98,7 %	33	100416-12/11

Average: 98,8 %

Separation degrees of full amalgam separator with minimal flow rate:

Nr.	Separation degrees [%]	Proben Nr.	Chargen Nr.:
1	99,0 %	25	100416-12/11
2	98,9 %	23	100416-12/11
3	98,7 %	28	100416-12/11

Average: 98,9 %

Value of the efficiency with maximum flow rate: 98,7%

Amalgam Separator pass the separation degrees test.