

Particle size analysis report (electron microscopy)

Demo · Sample DEMO · 2026-10-21

DEMO — the analysed images are synthetic, generated with known particle sizes. The validation table compares the measured values with the true ones.

Main results

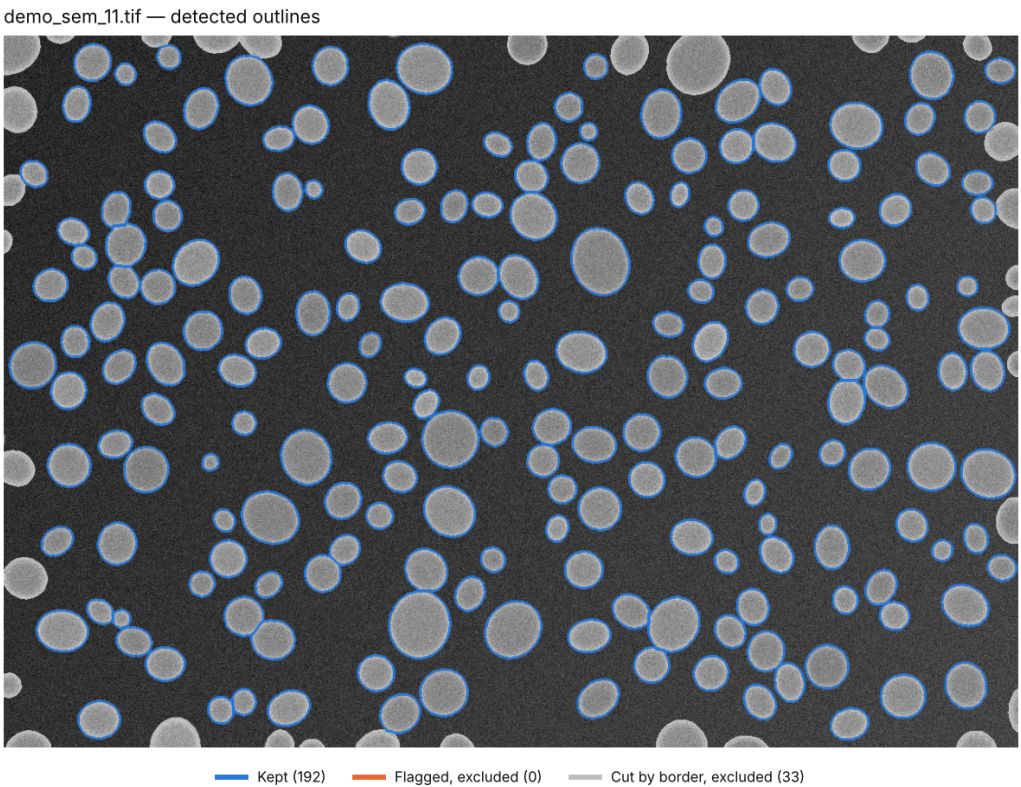
Quantity (number-based statistics)	Mean ± SD	D10	D50	D90
Area-equivalent diameter (nm)	70.2 ± 18.8	47.8	68.4	93.8
Minimum Feret diameter (nm)	66.2 ± 17.9	44.8	64.0	88.8
Maximum Feret diameter (nm)	77.4 ± 20.5	53.2	76.0	102.9

95 % confidence interval (area-equivalent diameter, nm)	Mean	D10	D50	D90
Bootstrap, 10,000 resamples	68.7 – 71.8	46.3 – 49.4	67.0 – 70.3	91.2 – 97.1

Precision reached on D50: ± 2.5 %. About 875 particles would give ± 2 % (uncertainty falls as 1/√n). This interval covers sampling uncertainty, not measurement bias (edge blur, thresholding), which calibration addresses.

Particles measured	580 (from 3 images)
Spread ((D90 – D10) / D50; CV)	0.67; 27 %
Median aspect ratio; median circularity	1.17; 0.92
Number fraction with minimum Feret ≤ 100 nm	95 % · EU nano criterion met
Pixel size	1.600 nm/px (scale bar 200 nm = 125 px)
Excluded objects	97 cut by the image border · 0 flagged (likely agglomerates, to check)

Segmentation check (image 1)



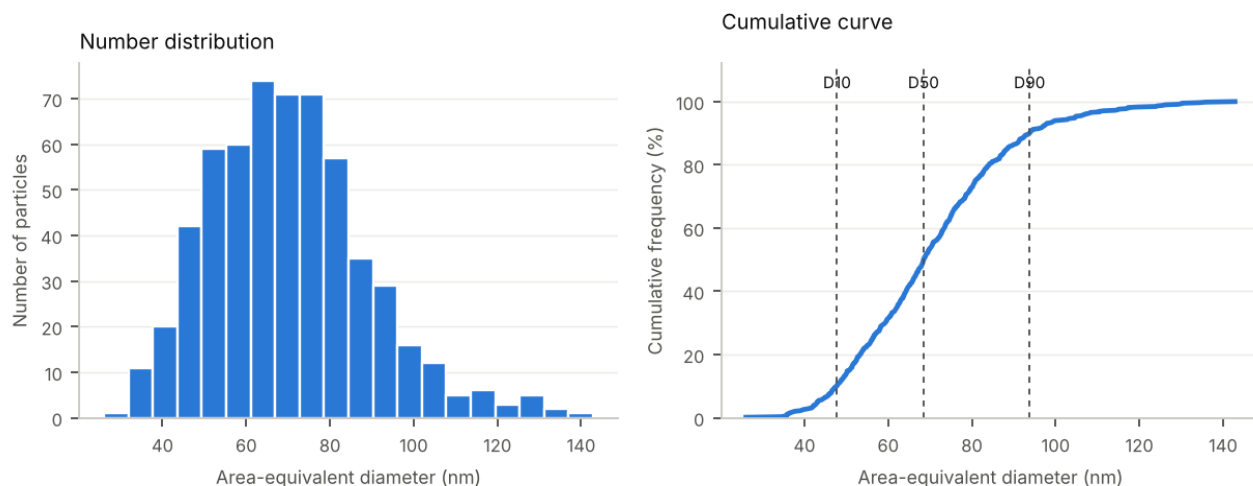
Nanomaterial screening (EU definition, Recommendation 2022/C 229/01)

Criterion met. 95.3 % of the measured particles have a smallest dimension (minimum Feret) ≤ 100 nm. Allowing for sampling, calibration and edge blur, the fraction lies between 91.3 % and 97.9 %, above the 50 % threshold: the material most likely meets criterion (a) of the definition.

Particles assessed (kept)	580
Number fraction with minimum Feret ≤ 100 nm	95.3 % (553/580)
95 % interval (sampling, Wilson method)	93.3 % – 96.8 %
Interval with calibration (± 2 %) and edge blur (± 3.2 nm)	91.3 % – 97.9 %
Median minimum Feret (95 % CI)	64.0 nm (62.4 – 66.1 nm)
Fraction when flagged objects are also counted (0)	95.3 %
Smallest detectable particle	≈ 10 nm · 62 px per 100 nm

Method. Criterion (a) of the Commission Recommendation of 10 June 2022: a material is a nanomaterial if 50 % or more of its particles, in the number-based size distribution, have at least one external dimension between 1 and 100 nm, whether on their own or as constituent particles of aggregates or agglomerates. On an image, the smallest external dimension is approximated by the minimum Feret diameter (smallest width of the projection). The verdict compares with the 50 % threshold an interval that combines sampling (Wilson) and a systematic band for calibration and edge blur. Not assessed here: the volume specific surface area (a material below $6 \text{ m}^2/\text{cm}^3$ is not a nanomaterial), criteria (b) and (c) (dimensions below 1 nm) and the thickness of platelets lying flat. Screening for internal use: it does not replace a regulatory determination.

Particle size distribution



Results per image

Image	Kept	Flagged	Border	D50 (nm)	Mean (nm)
demo_sem_11.tif	192	0	33	68.3	69.7
demo_sem_23.tif	192	0	32	70.5	72.4
demo_sem_37.tif	196	0	32	66.8	68.6

A small spread between images means the sampling is homogeneous; a large one suggests adding fields of view.

Validation against ground truth (synthetic images)

Quantity	Ground truth	Measured	Difference
D10 (nm)	45.4	47.8	+5.3 %
D50 (nm)	66.0	68.4	+3.7 %
D90 (nm)	91.1	93.8	+3.0 %
Mean (nm)	67.7	70.2	+3.7 %
Particles	578	580	+0.3 %

On synthetic images the true diameters are known, so this table measures the error of the whole chain (blur, noise, touching particles, thresholding). The small positive bias (about one pixel on the radius) comes from edge blur and is

removed by calibration on reference images.

Method

Pixel size read from the microscope metadata (Zeiss or Thermo Fisher TIFF) or derived from the scale bar in the data band (length detected automatically); both are compared when available, and the source used is shown in the parameters table. Gaussian smoothing ($\sigma = 1.5$ px), Otsu threshold, morphological opening and hole filling. Touching particles are split with a watershed on the distance transform. Objects cut by the image border are excluded. Objects with solidity < 0.90 or aspect ratio > 2 are flagged as likely agglomerates and excluded from the statistics. Feret diameters are computed on the convex hull (1° angular step). Number-based statistics, empirical percentiles. The approach follows the counting logic of the European recommendation 2022/C 229/01 (number-based distribution, minimum Feret diameter, at least 300 particles for the distribution, 500 for the nanomaterial screening).

Quality checks

Automatic check	Value	Status
Scale consistent (images, metadata, scale bar)	spread 0.0 %	pass
Particles kept	580	pass
Statistical precision on D50 (95 % CI)	± 2.5 %	pass
Resolution (D10 in pixels)	30 px	pass
Flagged objects (likely agglomerates)	0 %	pass
Objects cut by the border	14 %	pass
Consistency between images (max deviation from overall D50)	3 %	pass
Particle / background contrast (separability)	0.93	pass
Saturated pixels	0.0 %	pass
Visual review of the outlines by an analyst	—	not done (automated run)

Delivered files

This report (PDF) · particles.csv (one row per object: status, diameters, Feret, shape) · a control image per analysed image · summary.json.

Traceability

Item	Value
Analysis engine version	2.3.0
Parameters	sigma_lissage_px = 1.5, aire_min_px = 30, solidite_min = 0.9, aspect_max = 2.0, bootstrap_tirages = 10000, bootstrap_graine = 0, precision_cible_d50 = 0.02, nano_seuil_nm = 100.0, nano_fraction_seuil = 0.5, nano_n_conseille = 500, nano_px_par_100nm_min = 10, nano_incertitude_echelle_min = 0.02, nano_biais_bord_px = 2.0
SHA-256 fingerprint of demo_sem_11.tif	3b2095309539de18...
SHA-256 fingerprint of demo_sem_23.tif	1cb5c230295d2cd0...
SHA-256 fingerprint of demo_sem_37.tif	24e5e512b8671561...

The same images and engine version always give exactly the same results.

Limitations

Automated image analysis: sample preparation, image acquisition and the representativeness of the fields of view are the responsibility of the user. Not an accredited (ISO/IEC 17025) measurement: results are meant for R&D and internal quality control, not for regulatory declarations. A 2D projection does not measure thickness.

Analysis: Automated analysis