

Advancing Medical Device Biocompatibility Testing with New Approach Methodologies

Regulatory updates and industry case studies

Andy Forreryd, PhD

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Short introduction

Biocompatibility testing of Medical Devices and New Approach Methodologies (NAMs)

Table 1 — Biological effects for medical devices in contact with intact skin

Duration	Biological effect[a b c]							
	Cytotoxicity (6.5.2)	Sensitization (6.5.3)	Irritation (6.5.4)	Systemic toxicity (6.5.5)[d]	Local effects after tissue contact (6.5.6)	Genotoxicity (6.5.7)	Carcinogenicity (6.5.8)	Haemocompatibility (6.5.9)
A – limited (≤24 h)	E	E	E					
B – prolonged (>24 h to 30 d)	E	E	E					
C – long-term (>30 d)	E	E	E					

Table 2 — Biological effects for medical devices in contact with intact mucosal membranes

Duration	Biological effect[a b c]							
	Cytotoxicity (6.5.2)	Sensitization (6.5.3)	Irritation (6.5.4)	Systemic toxicity (6.5.5)[e]	Local effects after *tissue* contact (6.5.6)[d]	Genotoxicity (6.5.7)	Carcinogenicity (6.5.8)	Haemocompatibility (6.5.9)
A – limited (≤24 h)	E	E	E					
B – prolonged (>24 h to 30 d)	E	E	E	E	E	E		
C – long-term (>30 d)	E	E	E	E	E	E	E	

ISO 10993-1:2025

The following endpoints needs to be evaluated for nearly all Medical Devices:

- Cytotoxicity (ISO 10993-5)
- Irritation (ISO 10993-23)
- Sensitization (ISO 10993-10)

"The conduct of any in vivo biological testing shall be minimized to that which is strictly necessary to complete the biological evaluation"

" …..shall replace the use of animal testing with alternative techniques (e.g. in vitro or in silico) where methods provide equally relevant information to that obtained from in vivo models"

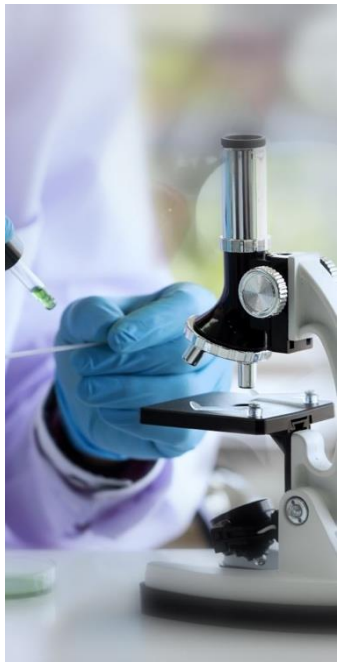
ISO 10993-1:2026

→ How much progress have we made within the MD sector to transfer from animals to NAMs?

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Transition from animal testing to NAMs

Status for the “big three” endpoints in medical device biocompatibility



Cytotoxicity

- NAMs included in ISO 10993-5.
- Accepted globally.

Irritation

- NAMs included in ISO 10993-23.
- Accepted in multiple regions (98% of the world)
- Not yet fully recognized by FDA.

Skin Sensitization

- NAMs included in Annex C of ISO 10993-10.
- Currently undergoing validation for full inclusion into ISO 10993-10.

Irritation testing in EU

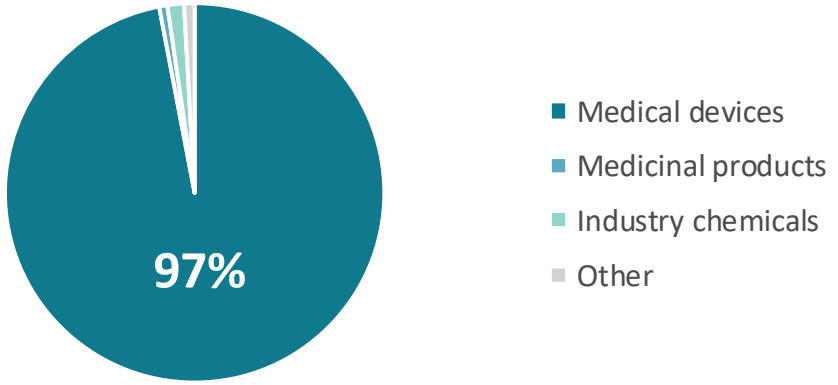
Most industry sectors have transitioned to NAMs – the MD sector is expected to follow

Irritation testing in the Medical Device sector

- A total of ~3,000 animals were used for regulatory skin and eye irritation/corrosion testing in EU in 2023.
- Almost all animal testing for this endpoint is conducted within the medical device sector (97%).
- Other industrial sectors has replaced animal tests with *in vitro* OECD test guidelines (TG 439/492).

→ However, the inclusion of NAMs in ISO 10993-23 is expected to accelerate regulatory acceptance and broader adoption of non-animal irritation testing in the MD sector.

In 2023, 97% of EU regulatory irritation animal testing is performed for medical devices



Source: ALURES published data, reporting year 2023, EU and Norway

REFERENCE: ALURES – ANIMAL USE REPORTING
EU SYSTEM EU STATISTICS DATABASE ON THE USE OF ANIMALS FOR SCIENTIFIC PURPOSES UNDER DIRECTIVE 2010/63/EU

Skin sensitization testing in EU

The largest remaining animal-use bottleneck in medical device biocompatibility

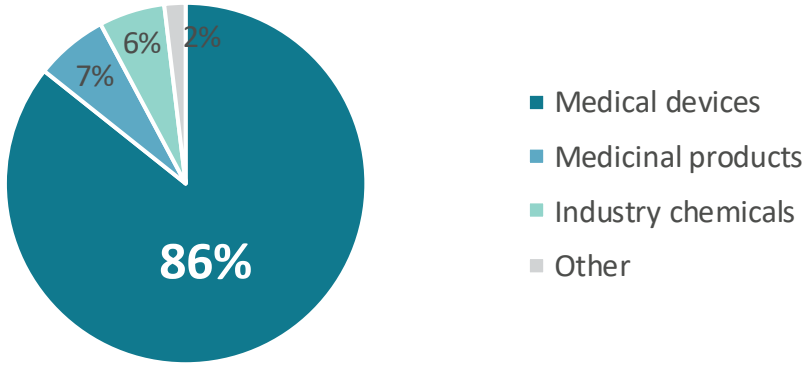
Skin Sensitization testing in the Medical Device sector

- A total of ~29,000 animals were used for regulatory skin sensitization testing in EU in 2023.
- Almost all animal testing for this endpoint is conducted within the medical device sector (86%).
- Other industrial sectors has replaced animal tests with *in vitro* OECD test guidelines (TG 442C,D,E & TG 497)

Notably slower uptake of NAMs in the Medical device sector.

Not because other sectors do not test for these endpoints, but because they have replaced historical animal studies with NAMs from OECD TGs.

86% of EU regulatory skin sensitization animal testing is performed for medical devices



Source: ALURES published data, reporting year 2023, EU and Norway

REFERENCE: ALURES – ANIMAL USE REPORTING
EU SYSTEM EU STATISTICS DATABASE ON THE USE OF ANIMALS FOR SCIENTIFIC PURPOSES UNDER DIRECTIVE 2010/63/EU

Biocompatibility testing of Medical Devices

In vitro skin Irritation testing according to ISO 10993-23

In vitro skin Irritation testing according to ISO 10993-23:2021 (Replace Rabbit testing)

- Based on commercially available Reconstructed Human Epidermis (RHE) models.
- The Medical Device is extracted according to ISO 10993-12 in polar and non-polar vehicles.
- OECD 439 protocol modified to compensate for highly diluted extracts by increasing incubation time.
- Spectrophotometric measurement (MTT)
- Cell viability ≤50% = irritant (GHS cat. 2)
- Read out: Skin irritant or non-irritant



Cytotoxicity ISO 10993-5	**Skin irritation** ISO 10993-23	**Skin Sensitization** ISO 10993-10

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Biocompatibility testing of Medical Devices

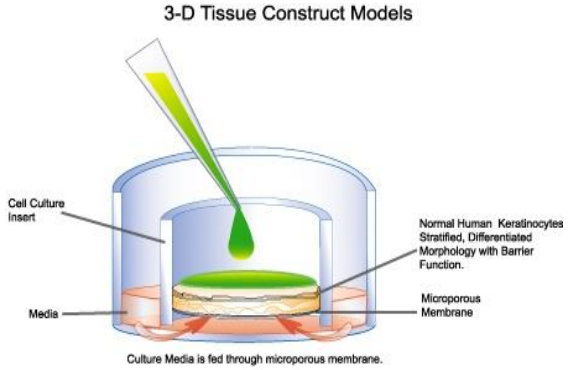
In vitro skin Irritation testing according to ISO 10993-23

Successful completion of round robin study and update to the ISO 10993-23 in 2021:

- → **Extractables:** *In vitro* shall replace all animal testing.
- **Non-extractables:** *In vitro* accepted on a case-to-case basis
- **Special Irritation test** (Annex D): May be appropriate to use alternative in vitro 3D reconstructed human epithelial tissue models such as eye, nasal, oral, vaginal.

Note: Most countries fully recognizes the *in vitro* methods, including EU, UK, Japan etc. Work is ongoing in WG8 to address the concerns from FDA.

Predictivity:	95-100%
Within lab reproducibility:	85-100%
Between lab reproducibility:	90-100%



ISO 10993-23:2021

Biological evaluation of medical devices — Part 23: Tests for irritation

Biocompatibility testing of Medical Devices

Skin sensitization testing according to ISO 10993-10

Skin sensitization testing according to ISO 10993-10:2021

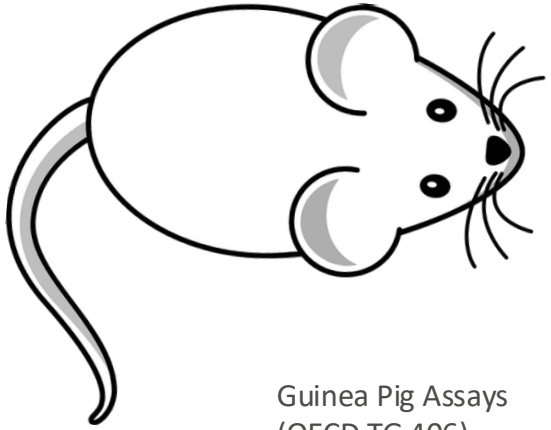
- Skin sensitization has historically been evaluated using animal methods:
  - Local Lymph Node assay (LLNA)
  - Guinea Pig Maximization Test (GPMT)
  - Buehler Test
- The new version of ISO 10993-10:2021 includes *in vitro* assays and proposes a step-wise approach where animal models shall only be used as a last resort.

Can we leverage *in vitro* tools in OECD TG 442?

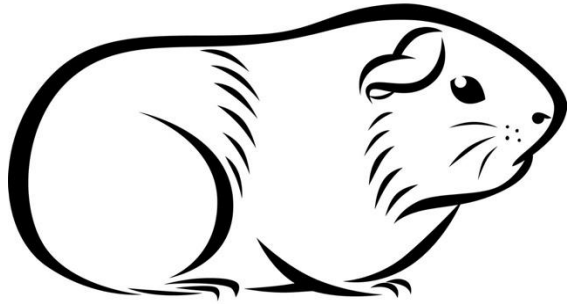
→ The scientific tools exist. The remaining challenge is standardization, **regulatory (and industry) acceptance**, and implementation.

Cytotoxicity ISO 10993-5	**Skin Irritation** ISO 10993-23	**Skin Sensitization** ISO 10993-10

LLNA
Local Lymph Node Assay (OECD TG 429)



Guinea Pig Assays
(OECD TG 406)

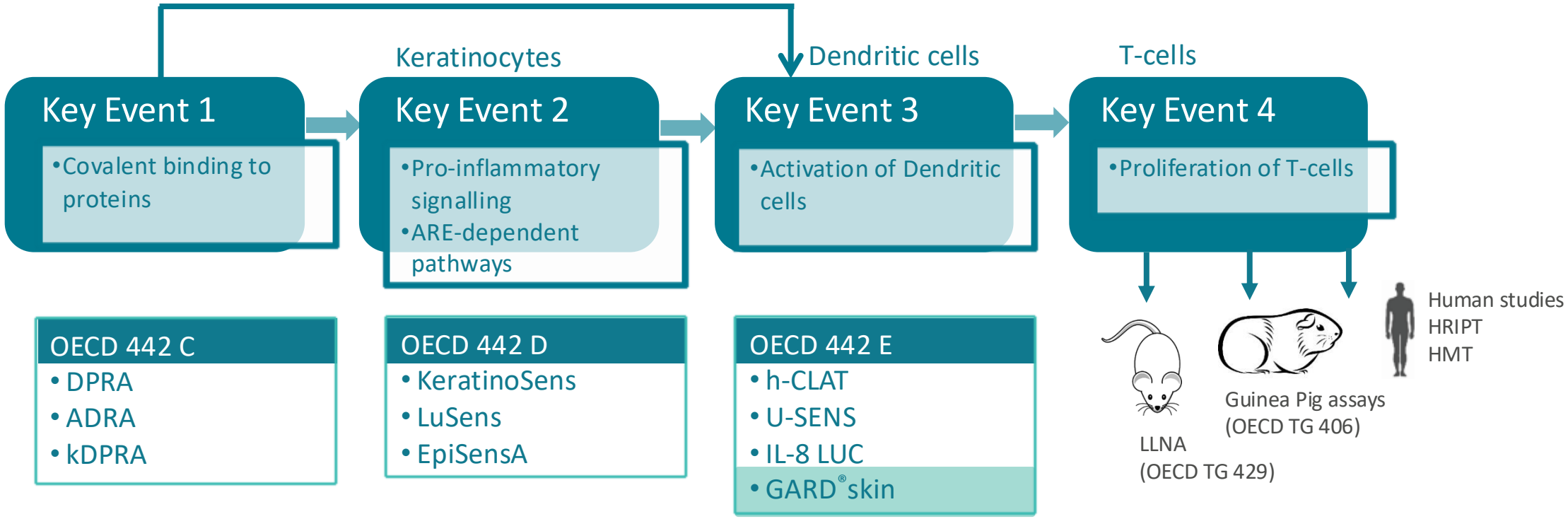


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In vitro methods for skin sensitization

OECD Test Guidelines are mapped to the AOP

AOP - Adverse Outcome Pathway
NAM - New Approach Methods (KE 1-3)



Note: Only 2 of the 10 OECD validated assays have demonstrated compatibility for medical device testing (polar and non-polar solvents, ISO 10993-12). **GARDskin** will be used as a proof-of-concept since it has progressed the furthest towards full regulatory implementation.

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EpiSens A

(OECD TG 442 D)

Key technological features:

Reconstructed human Epidermis and transcriptomic readout



EpiSensA for medical device testing

Initial in-house testing to confirm applicability and performance

The EpiSens A test method for chemicals

- OECD Test Guideline 442 D
- Based on a Reconstructed Human Epidermis
- (LabCyte EPI-Model 24)
- Gene expression changes of four biomarker genes: ATF3, GCLM, DNAJB4, IL-8

Adaptation for medical device testing (ongoing)

- Extractions according to ISO 10993-12 – direct application of polar and non-polar solvents.
- Work is ongoing in Japan to further evaluate applicability for device testing.
- Initial in-house data (SenzaGen) promissing, but some concerns about sensitivity.

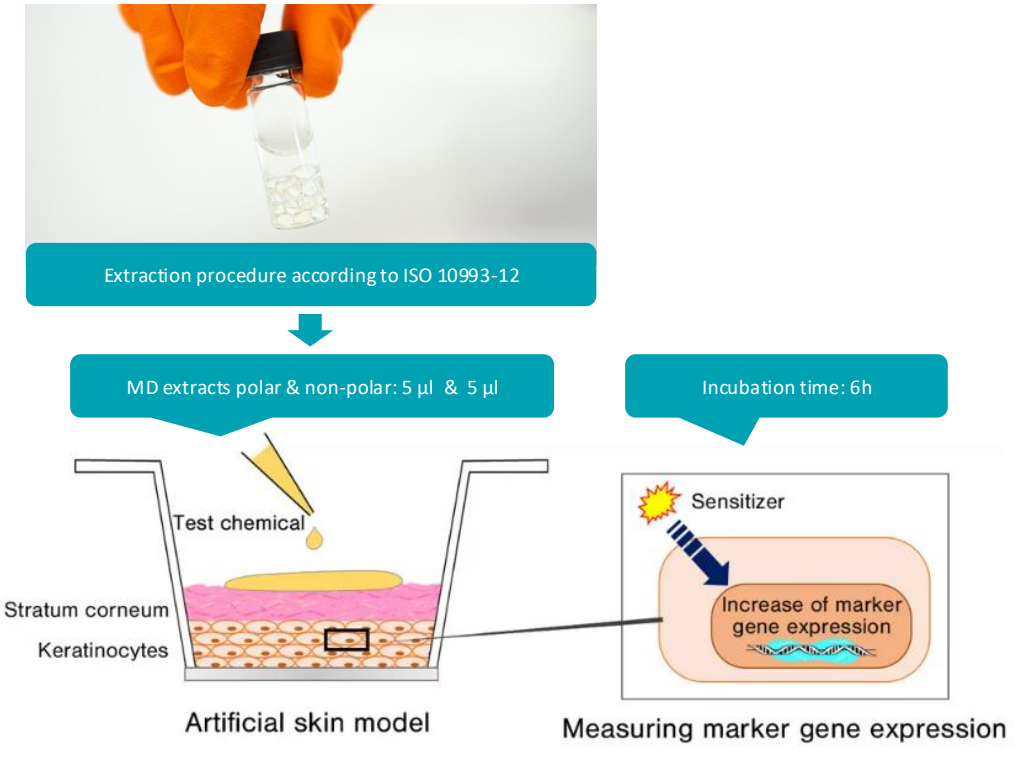


Figure 1. Representation of EpiSensA testing (Original image source: KAO)

At least one of the gene expression induction level exceeds the respective defined cut-off value under sub-cytotoxic conditions → skin sensitizer

GARD®

Genomic Allergen Rapid Detection™

Key technological features:

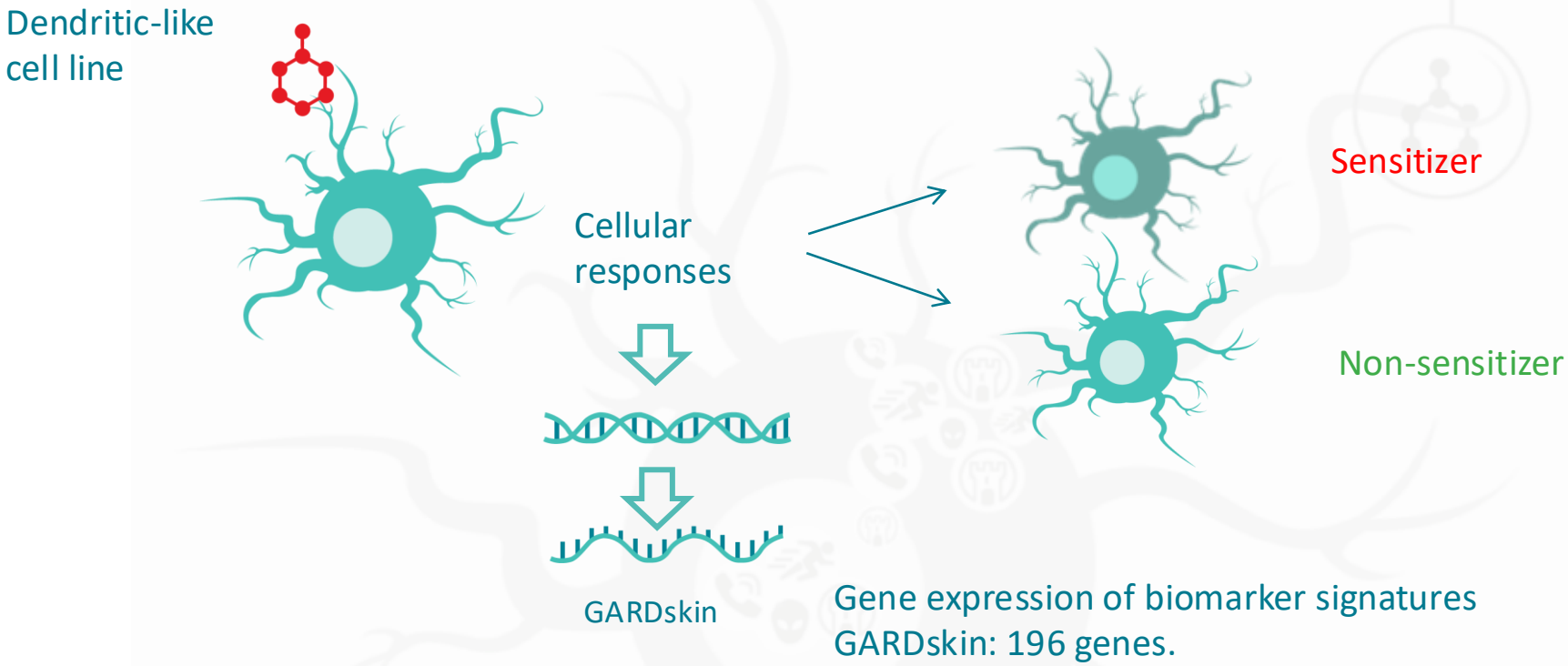
Genomics and machine learning



The GARD technology platform – how it works

Transcriptomic read-out of the biological response

Biological system: Dendritic-like cell line (KE3)
Readout: Gene expression (genes and toxicity pathways)

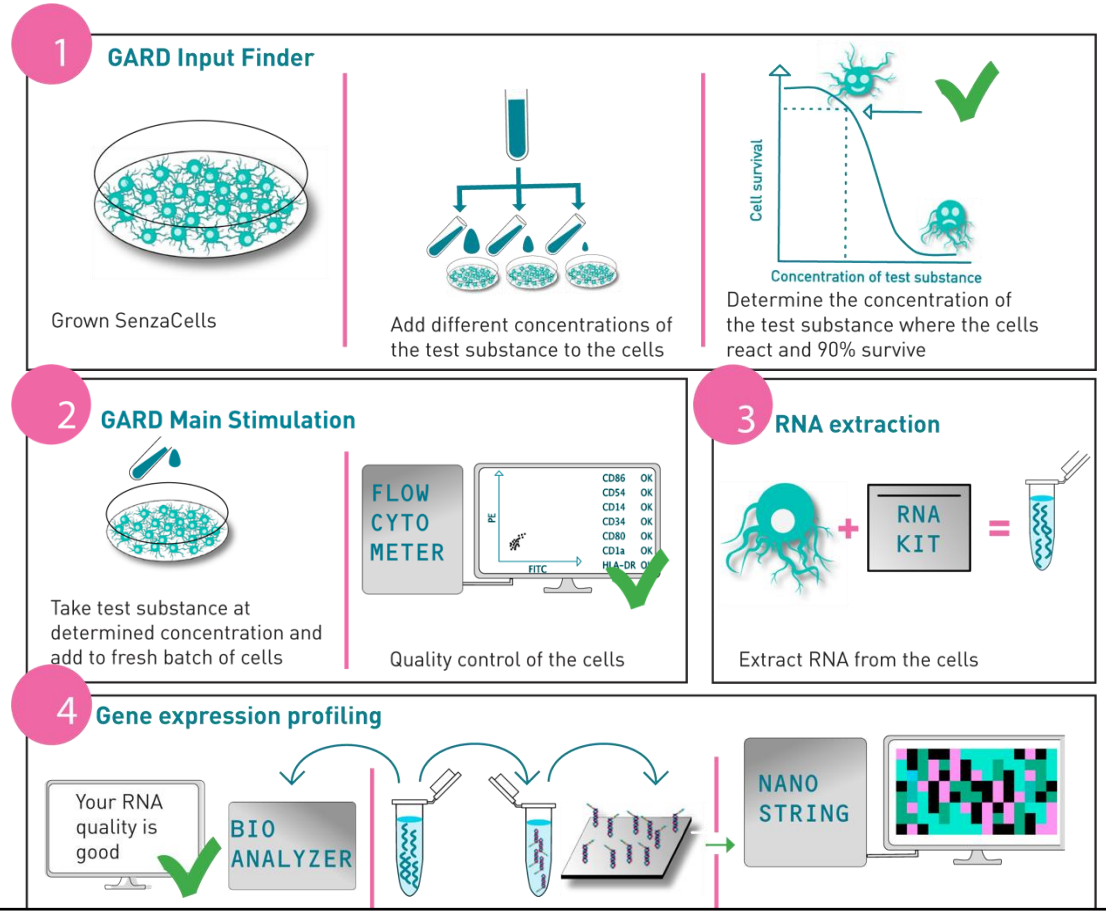


Full transparency: Identities of genes being measured available in peer-reviewed scientific literature.

See for example: Johansson et al. (2011) A genomic biomarker signature can predict skin sensitizers using a cell-based in vitro alternative to animal tests. BMC Genomics.

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How to GARD your products in 6 Steps



Importantly: All genes contributes to a final classification, but with different weights

Prediction algorithm:

$$DV = b + \sum_{i=1}^{n} w_i x_i$$

n: number of variables (n for GARDskin:196)
b: constant (SVM intercept)
W_i: weight for variable i
X_i: Normalized gene expression data for variable i

Prediction model:
Mean DV ≥ 0 : Skin sensitiser (UN GHS category 1)
Mean DV < 0 : Non-sensitiser.

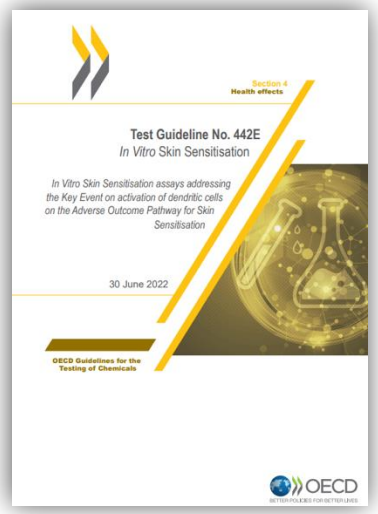
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The OECD approval of GARD®skin

Extending the applicability domain of NAM-based assays in OECD TG 442

OECD Test Guideline No. 442 E - *In Vitro* Skin Sensitisation

KE 3 in the AOP for skin sensitization: DCs activation



Performance statistics:

GARDskin accuracy:	**94%**
WLR	**82.1- 88.9%**
BLR	**92%**

→ Adaptation and validation of the method for device testing follows the guidelines established in ISO TS 11796

Applicable for testing a variety of chemicals of relevance for the medical device industry.

Metals and metal salts

Johnson & Matthey: Forreryd, A. et al. (2022). The GARD™ skin assay: Investigation of the applicability domain for metals.

Complex mixtures

Corteva: Corvaro, M., et al. (2024). GARD™ skin and GARD™ potency: a proof-of-concept study to investigate the applicability domain for agrochemical formulations.

Polymeric materials

DSM: *In vitro* assessment of skin sensitizing potential of process-related impurities in polymeric materials during product development. Poster.

GARDskin: Published in Johansson et al. (2019), Validation of the GARD™ skin assay for assessment of chemical skin sensitizers - ring trial results of predictive performance and reproducibility. ***Toxicological Sciences.***

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In vitro skin sensitization testing of medical devices

GARDskin MD towards full implementation into ISO 10993-10

ISO/TS 11796 framework to demonstrate the applicability of NAM-based OECD TGs for testing skin sensitization potential of medical devices.

Step #1: Feasibility study

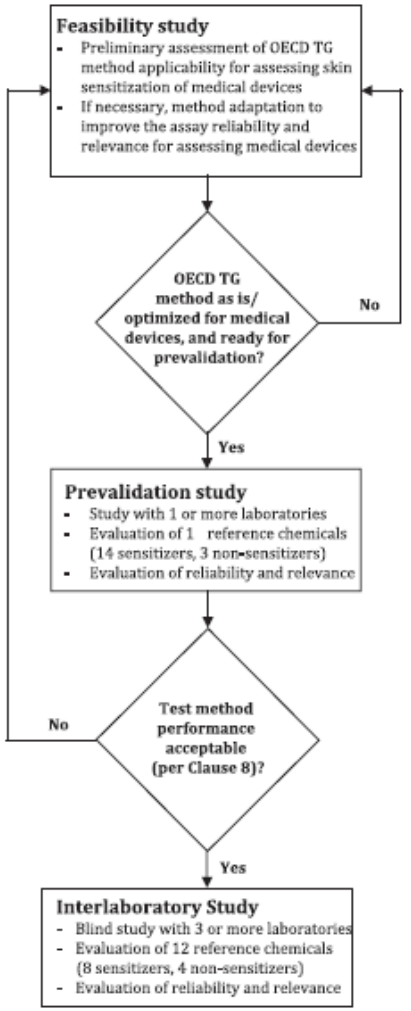
- Adaptation of protocols and preliminary assessment of applicability for assessing skin sensitization of medical devices.

Step #2: Prevalidation study

- Testing of extracts (n=16, 3 repeats) from MED-2000 spiked with sensitizers/non-sensitizers and prepared in both polar/non-polar vehicles.

Step #3: Interlaboratory study

- Testing of extracts (n=13, 3 repeats) from MED-2000 spiked with sensitizers/non-sensitizers and prepared in both polar/non-polar vehicles.



TECHNICAL SPECIFICATION **ISO/DTS 11796**

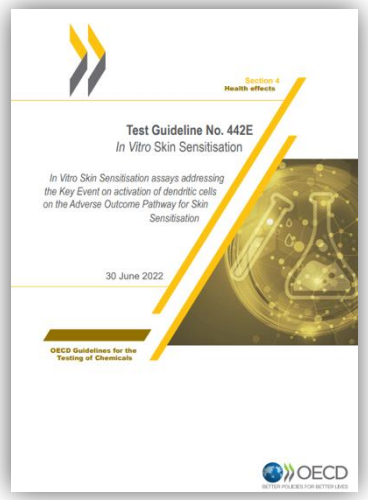
Biological evaluation of medical devices — Requirements for interlaboratory studies to demonstrate the applicability of validated in vitro methods to assess the skin sensitization of medical devices

GARDskin Medical Device

Feasibility study to demonstrate applicability

Background

- Modification of the OECD TG protocols to enable testing in polar and non-polar extracts of the device according to ISO 10993-12.
- Included in informative annex to ISO 10993-10.



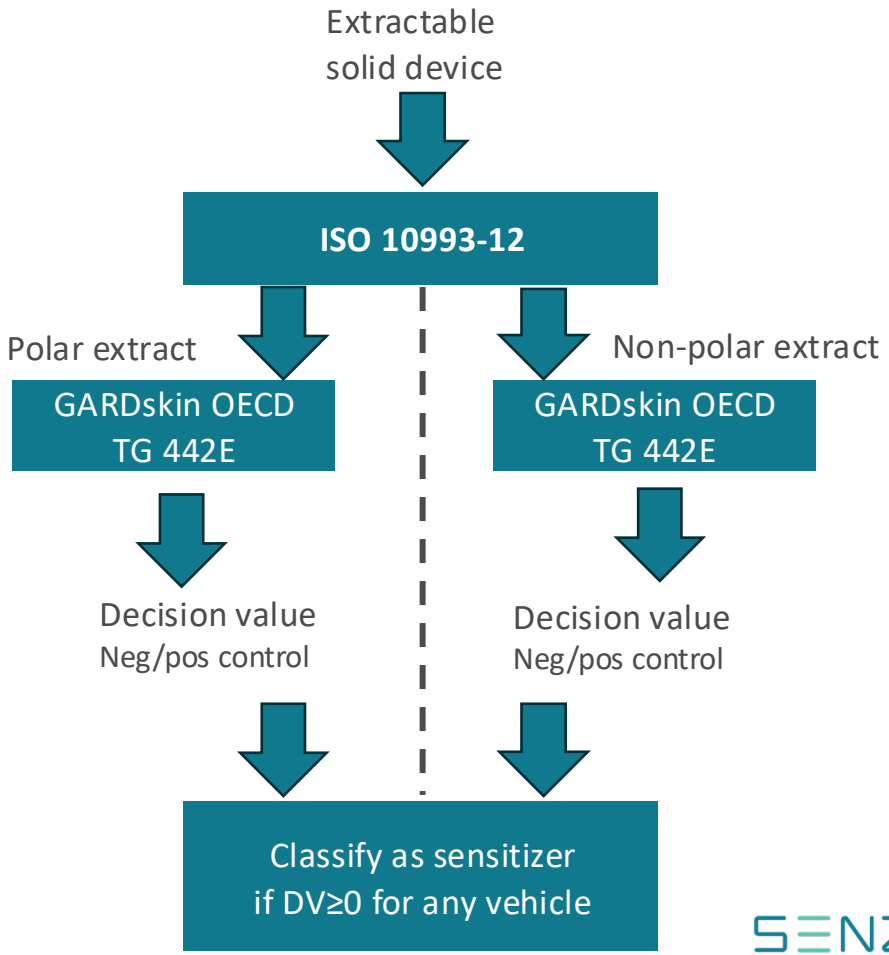
Sensitization testing of devices:
ISO 10993-10.

Biological evaluation of medical devices —

Part 10:
Tests for skin sensitization

Évaluation biologique des dispositifs médicaux –
Partie 10: Essais de sensibilisation cutanée

ISO



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Publication: Jenvert et al. (2023) Evaluation of the Applicability of GARDskin to Predict Skin Sensitizers in Leachables from Medical Device Materials. Frontiers in Toxicology

GARDskin Medical Device

Feasibility study to demonstrate applicability (2/2)

Proof-of-concept study designed to evaluate the functionality of the protocols for testing of extracts from medical devices.

Methods

- Polymeric materials spiked with skin sensitizers of different potency used as proxies for medical devices.

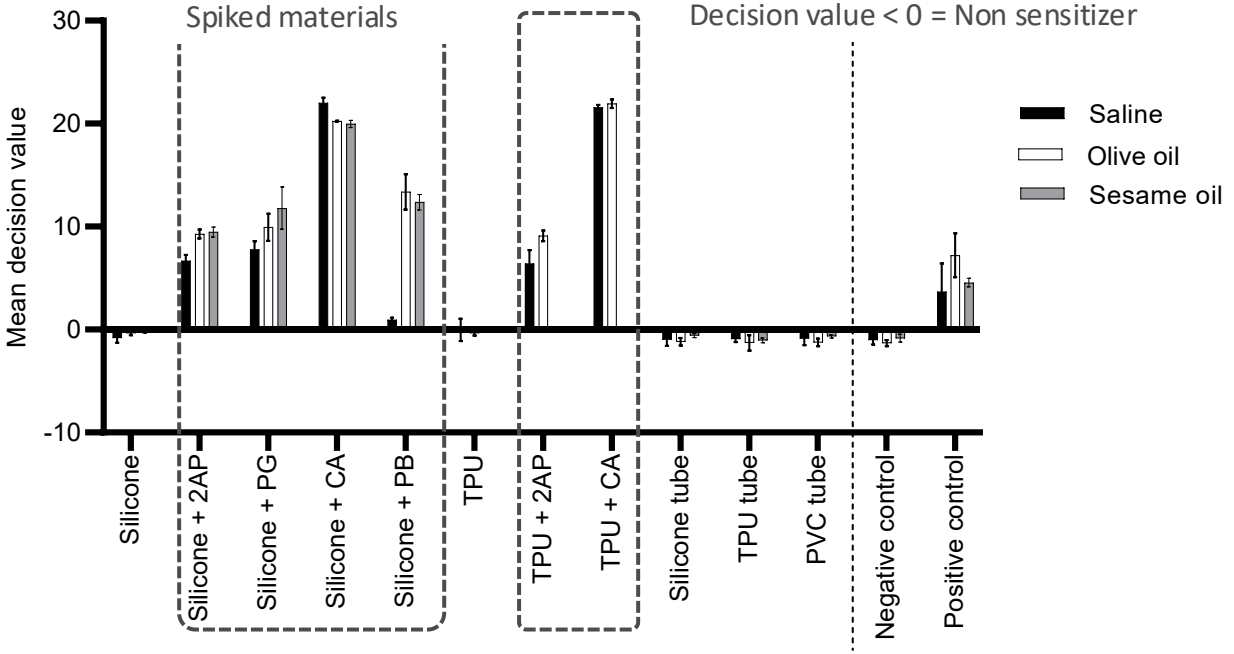
Results

- All spiked materials correctly predicted.
- No positive signals from medical grade materials.

Conclusions

- GARDskin Medical Device assay is compatible with both polar and non-polar extraction vehicles.
- Sufficiently sensitive to detect the presence of sensitizers in diluted and complex extracts from the polymeric materials.

GARDskin prediction model:
Decision value > 0 = Sensitizer
Decision value < 0 = Non sensitizer



"GARDskin can be applied to accurately predict the sensitizing potential of medical device polar and non-polar extracts, prepared according to established extraction procedures described in ISO 10993-12"

Publication: Jenvert et al. (2023) Evaluation of the Applicability of GARDskin to Predict Skin Sensitizers in Leachables from Medical Device Materials. Frontiers in Toxicology.

In vitro skin sensitization testing of medical devices

GARDskin MD towards full implementation into ISO 10993-10

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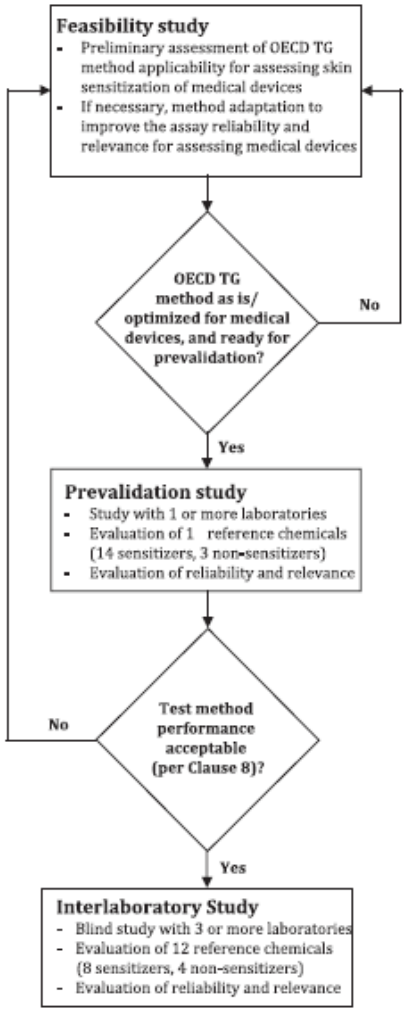
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TECHNICAL SPECIFICATION **ISO/DTS 11796**

Biological evaluation of medical devices — Requirements for interlaboratory studies to demonstrate the applicability of validated in vitro methods to assess the skin sensitization of medical devices

GARDskin Medical Device

Prevalidation study to evaluate method's reliability and relevance

Methods

- A negative control material (MED-2000) extracted in polar and non-polar vehicles and spiked with chemicals.
- A total of 29 chemicals evaluated at the lead laboratory. For 16 chemicals, repeated assessments were performed (n=3).

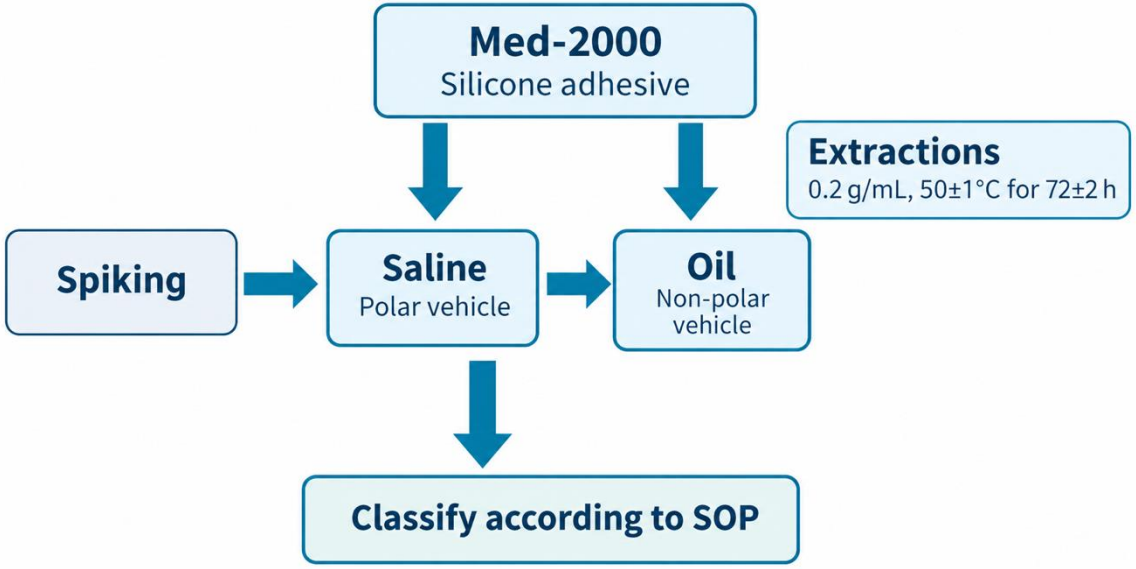


Table 1 — Database of reference chemicals for PRE and ILS

S/NS	Set	Name	CAS	Application in the medical device industry	Spiking concentration *w/v* %
S	PRE	Glutaraldehyde	111-30-8	Disinfectant and crosslinker for animal derived tissue product	0,08
S	PRE	1,4-Phenylenediamine	106-50-3	—	0,11
S	PRE	Phthalic anhydride	85-44-9	—	0,16
S	PRE	Cobalt chloride	7646-79-9	Orthopaedic implants, stents, pacemakers	0,4
S	PRE	Phenylacetaldehyde	122-78-1	—	3
S	ILS	Hydratropic aldehyde	93-53-8	—	6,3
S	PRE	Alpha-hexylcinnamaldehyde	101-86-0	Ink, lubricants, etc.	10,8
S	PRE	Linolenic acid	463-40-1	Lubricants	9,9
S	PRE	Ethyl acrylate	140-88-5	Acrylates, methacrylates and monomers Found in adhesives, wearable devices, wound dressings	10
S	PRE	TPO (diphenyl(2,4,6-trimethylbenzoyl) phosphine oxide)	75980-60-8	Photo-initiator for additive manufacturing in many light-cured acrylic polymers) such as composite materials, dental fillers, etc.	27
S	PRE	2,4,7,9-Tetramethyl-5-decyn-4,7-diol	126-86-3	Plastic and rubber products	34,3
S	PRE	Isopropyl myristate	110-27-0	Plasticizer, lubricant	44
S	PRE	Tridecane	629-50-5	Solvent, rubber industry	48,4
S	PRE	Methyl methacrylate	80-62-6	Bone cement, dental materials, hearing aids	75
NS	PRE	Diethyl phthalate	84-66-2	Solvent, plasticizer, extractable associated with polyethylene and PET	1
NS	PRE	1,3-diphenylguanidine	102-06-7	Rubber accelerators Found in gloves	1
NS	PRE	Zinc oxide	1314-13-2	Anti-bacterial and anti-biofilm activity	1
S	ILS	2,4-Dinitrochlorobenzen (DNCB)	97-00-7	—	0,06
S	ILS	Formaldehyde (act. 37 %)	50-00-0	Sterilization-low temperature steam and formaldehyde (LTSF)	0,3
S	ILS	Isobornyl acrylate (IBOA)	5888-33-5	Plastic materials, valves, tubes lining, stoppers, sealants, coatings, inks, glues Found in adhesives, wearable devices such as glucose monitoring sensors, insulin patch pumps and some wound dressings	1
S	ILS	2-Mercaptobenzothiazole (MBT)	149-30-4	Rubber accelerators Gloves	1,35
S	ILS	2-hydroxyethyl acrylate	818-61-1	Acrylates, methacrylates and monomers Wound dressings, EKG electrodes, contact lenses	1,4
S	ILS	Nickel(II) sulfate hexahydrate ($NiSO_4$)	10101-97-0 7786-81-4	Nickel alloys and stainless steels in implantable medical devices	4,8
S	ILS	Abietic acid	514-10-3	Adhesives Wound dressing	15

Key

S skin sensitizer

NS non-skin sensitizer

w weight

v volume

The database of reference chemicals contains 29 chemicals, 7 non-skin sensitizers and 22 skin sensitizers. The selected chemicals are distributed in two sets. The first set of 16 chemicals (13 skin sensitizers and 3 non-skin sensitizers) which shall be used for the prevalidation phase, are labelled "PRE" in Table 1 and are included in Clause A.1. The second set of 13 chemicals (9 sensitizers and 4 non sensitizers) which shall be used for the interlaboratory study phase, are labelled "ILS" in Table 1 and included in Clause A.2. The size of this set, 13 chemicals, represents half the number of chemicals originally used for the validation of OECD test methods. It was considered appropriate from a statistical point of view because minor deviation of the protocols during the feasibility study are unlikely to affect the transferability and interlaboratory reproducibility.

GARDskin Medical Device

Prevalidation study to evaluate method's reliability and relevance

Results

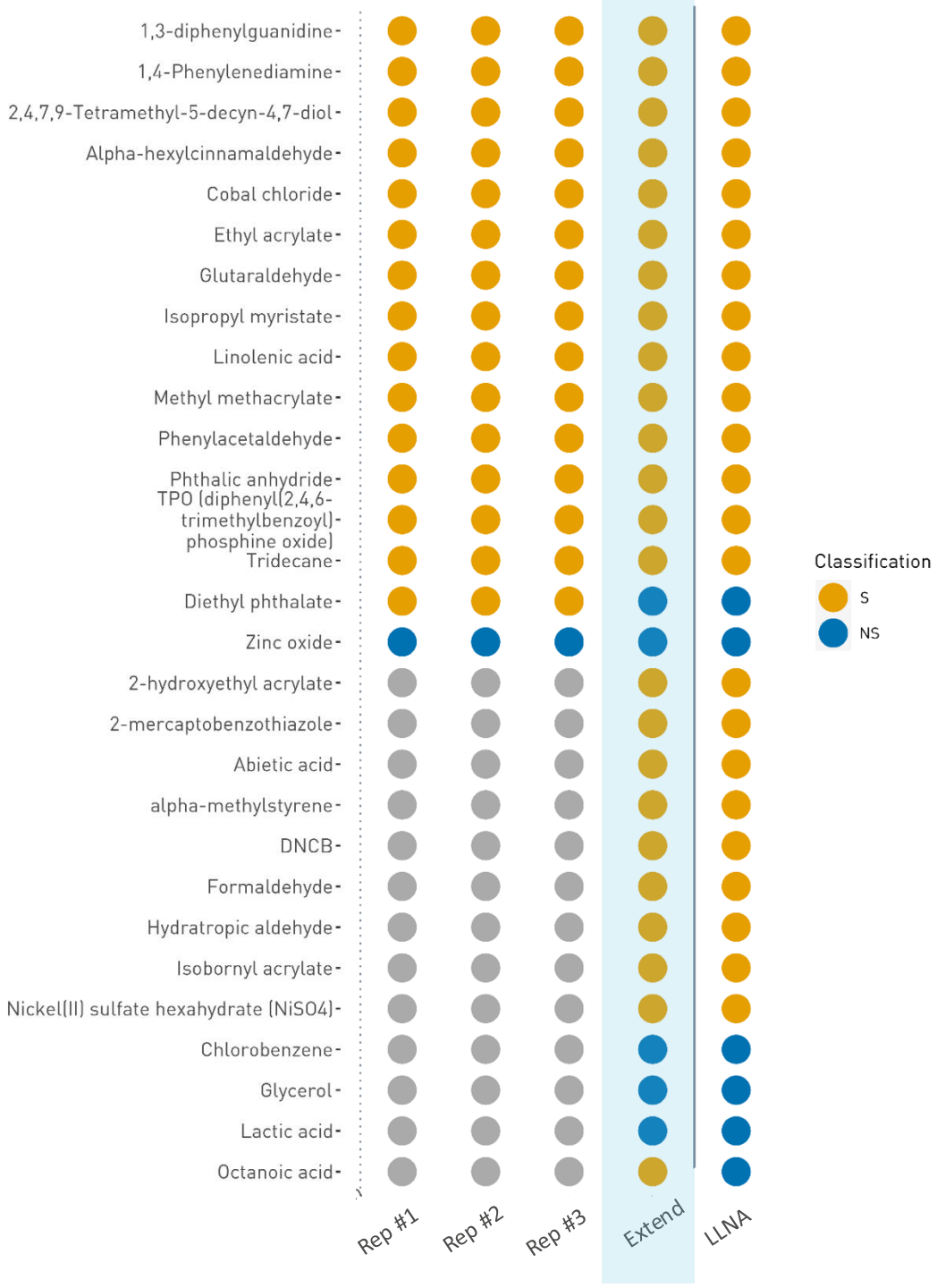
Reproducibility evaluated based on repeated testing of 16 chemicals (n=16, 3 replicates)

- **Reproducibility: 100% (16/16)**

Performance evaluated by extended testing of 29 chemicals. (n=19, 1 replicate)

- **Concordance to LLNA: 97% (28/29)**

ISO TC194 – WG8: GARDskin MD protocol is reliable and relevant, qualified for the final step in the validation procedure.



Redefining Biocompatibility Testing:

The growing role of NAMs in Product Development and regulatory submissions

Industry case studies



Case study #1

A non-animal based testing approach for CE-marking of devices according to MDR

Background

- *In vitro* testing for risk assessment of medical devices for CE – marking according to MDR.
- Medical device: Tinearity G1 – reduce the impact of tinnitus.

Methods

- Device intended for contact with intact skin.
- Testing performed *in vitro* for the following endpoints:
  - Cytotoxicity: ISO 10993-5
  - Skin Irritation: ISO 10993-23
  - Skin Sensitization (GARD): ISO 10993-10
- Extraction conditions (ISO 10993-12):
  - 72 ±2 h, at 37±1 °C
  - Saline and super refined Olive oil.
  - Extraction ratio of 3 cm^2/ml vehicle.





DUEARITY

Information on how SenzaGen's GARD®skin Medical Device assay may help obtain a CE-mark under the European Medical Device Regulation 2017/745 (MDR) is for informational purposes only and should not be construed as legal or regulatory advice or a guarantee of compliance with any law, regulation, or guideline. Therefore, we hereby disclaim any and all liability for any actions or direct, indirect, incidental, special, consequential, or other damages related to this information.

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Case study #1

A non-animal based testing approach for CE-marking of devices according to MDR

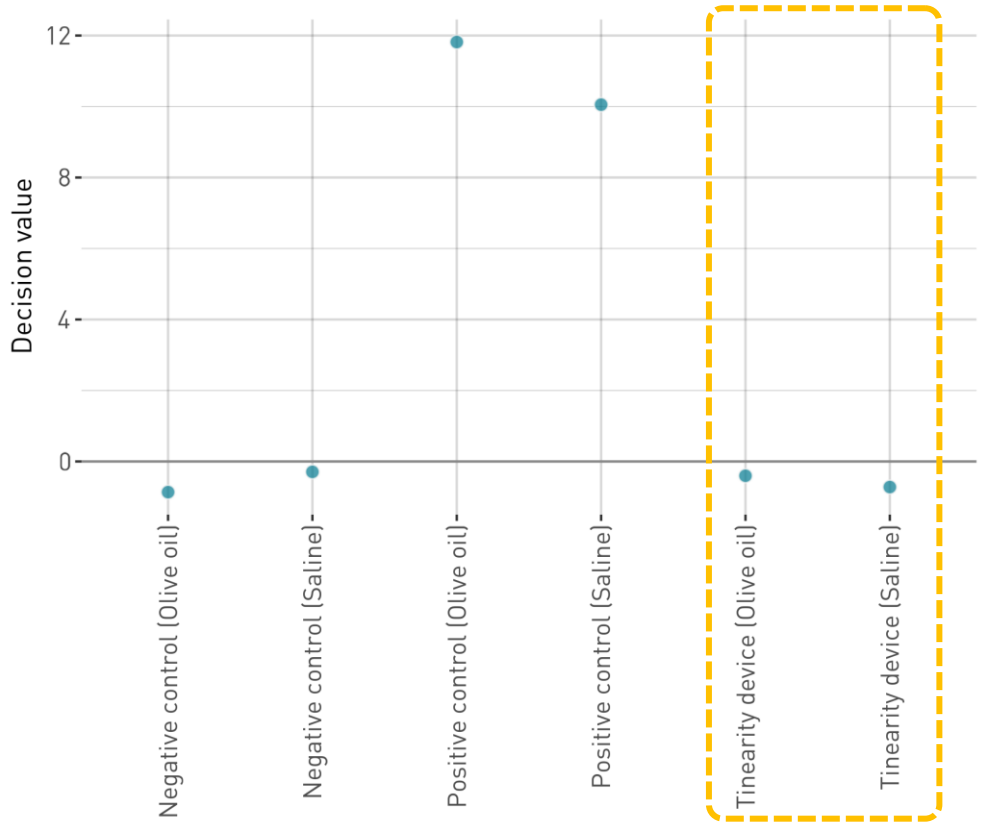
Results

- Results from testing of the device showed no hazard for evaluated endpoints.

Conclusion

- *In vitro* data used as WoE together with toxicological evaluation of chemical data and submitted as part of the technical file to Notified Bodies.
- No comments on the biocompatibility. Device accepted for CE marking and released on EU market.

Growing acceptance of *in vitro* data by EU Notified Bodies, with case reports from Japan and other countries. US FDA submissions are also underway, driven by early industry adopters committed to non-animal testing.



Information on how SenzaGen's GARD®skin Medical Device assay may help obtain a CE-mark under the European Medical Device Regulation 2017/745 (MDR) is for informational purposes only and should not be construed as legal or regulatory advice or a guarantee of compliance with any law, regulation, or guideline. Therefore, we hereby disclaim any and all liability for any actions or direct, indirect, incidental, special, consequential, or other damages related to this information.

Case study #2

In vitro biocompatibility “big three” testing of metallic 3D printing material

Background

- Supplier of metal-based additive manufacturing materials to the medical device industry.
- Test material produced using the Lithography-based Metal Manufacturing (LMM) technology.
- Objective: generate material-level biocompatibility data to support safety assessment and downstream device development.

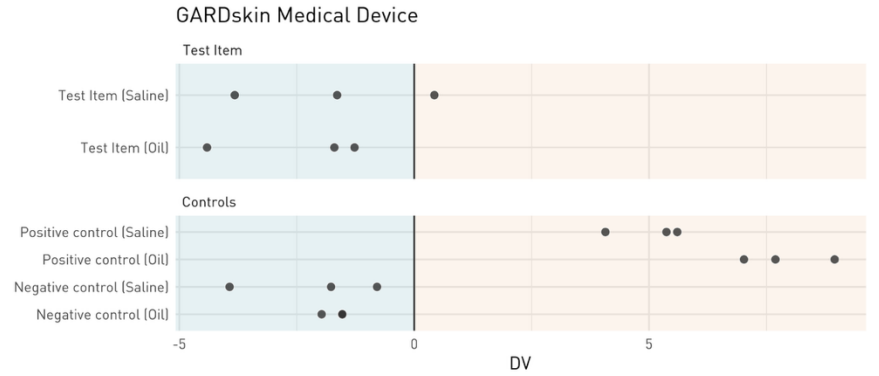
Methods

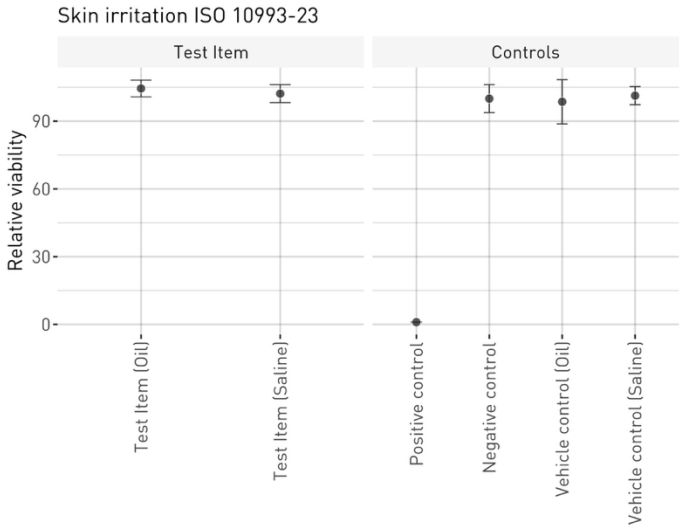
In vitro biocompatibility ”big three” testing:

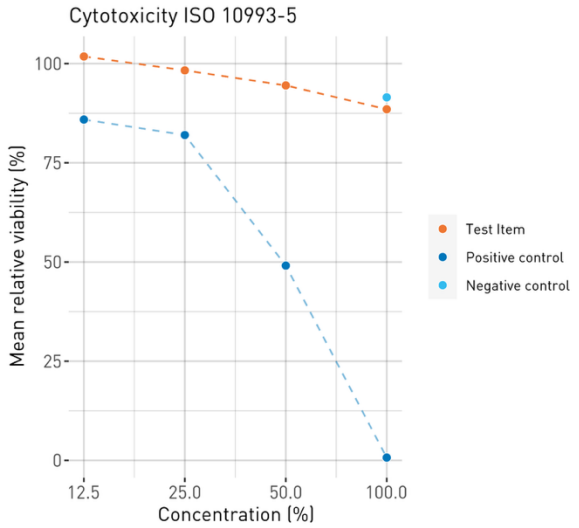
- Skin sensitization ISO 10993-10: GARDskin Medical Device.
- Skin irritation ISO 10993-23
- Cytotoxicity ISO 10993-5

Results

- Results showed no hazard for the three evaluated endpoints.







Illustrates the use of in vitro "Big Three" testing to efficiently generate biocompatibility data for additively manufactured metallic materials. Provides confidence in material safety prior to downstream device applications.

Case study #3

In vitro skin sensitization testing of 3D printed oral device

Background

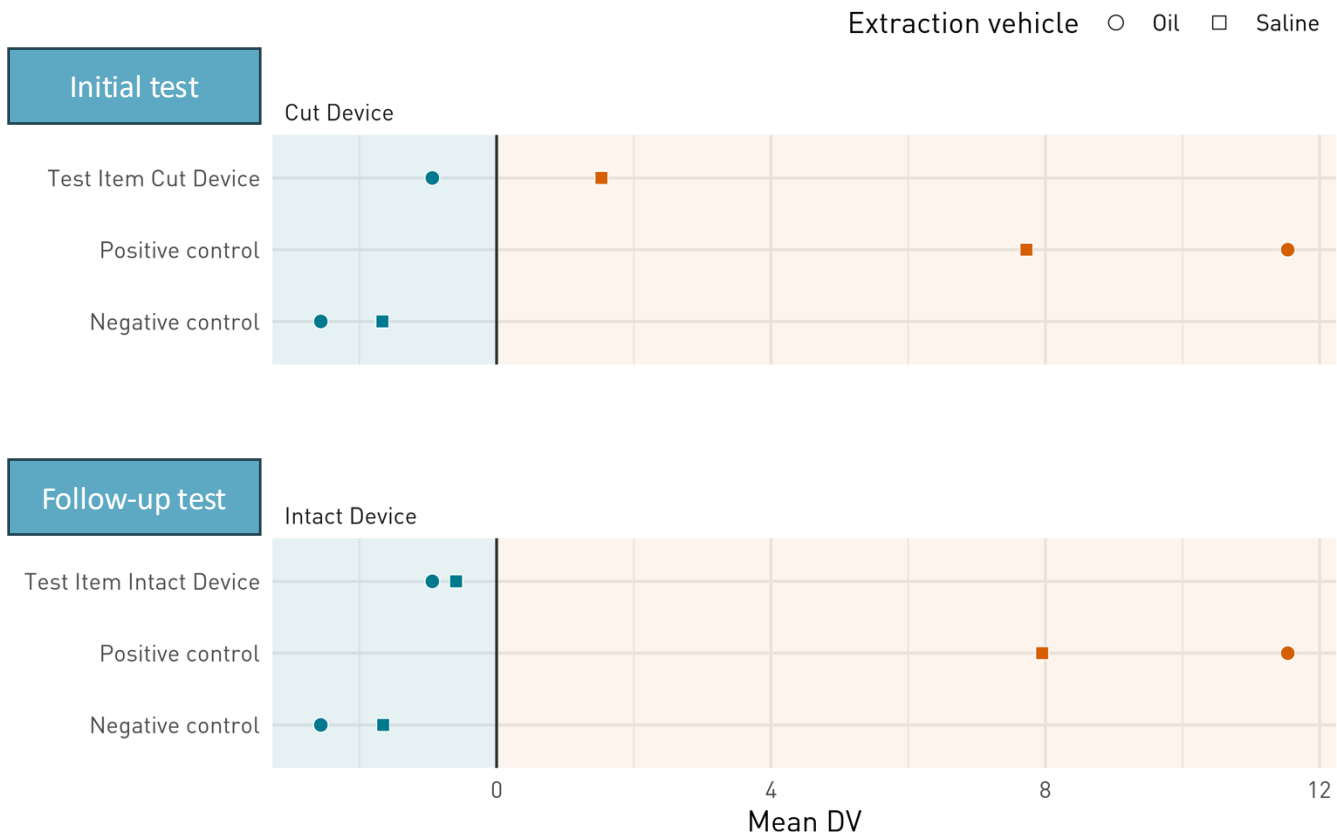
- 3D-printed oral device manufactured from a UV-cured crosslinked acrylate copolymer.
- Potential sensitization concern related to residual photopolymerization constituents, including unreacted monomers and photoinitiator-derived species.
- Chemical characterization indicated no sensitization-relevant leachables.

Methods

- Due to the large size of the final device, the initial GARDskin MD study was conducted on extracts from cut-device sections.
- Follow-up GARDskin MD test performed on full device.
- Material prepared according to ISO 10993-12 in polar and non-polar extraction vehicle (72h, 50°C, 3cm^2/ml).

Results

- Cut device: classification = sensitizer
- Full device: classification = non-sensitizer



Sample preparation can significantly impact sensitization outcomes for UV-cured materials.
The in vitro assay was sufficiently sensitive to detect signals potentially associated with incomplete curing.

Case study #4A

In vitro skin sensitization testing during product development (1/2)

Background

- Acrylic-based device.
- Coating consisting of a UV-cured lacquer.
- The surface of the device was irregular and contained cavities.

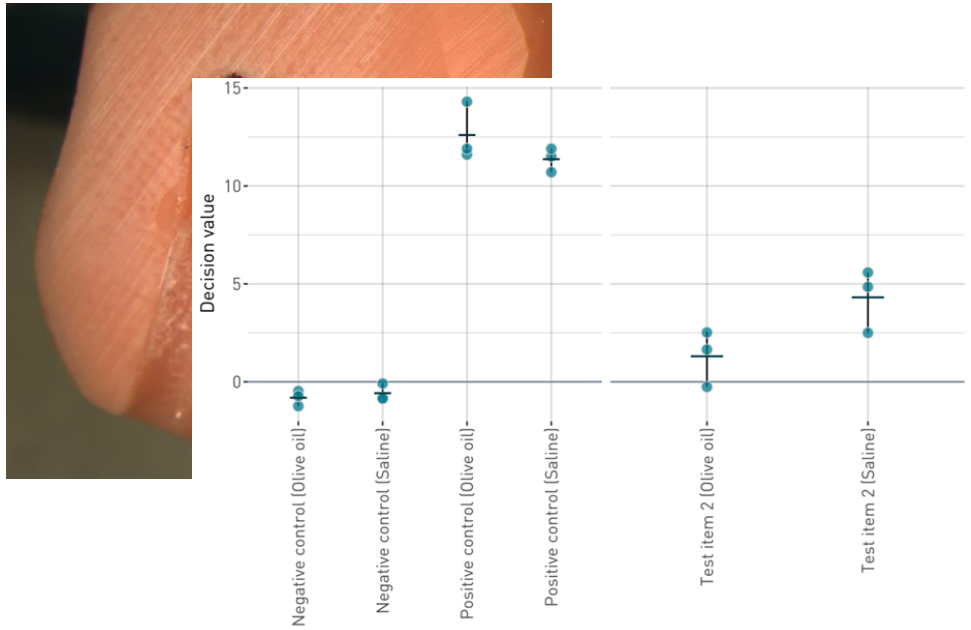
Methods

- GARDskin Medical Device.
- Material prepared according to ISO 10993-12 in polar and non-polar extraction vehicle (72h, 50°C, 3cm²/ml).

Results

- Positive in both polar and non-polar vehicles.
- Device initially classified as a sensitizer.

Hypothesis: Insufficient curing of the lacquer within cavities.



GARD® results for acrylic-based devices with cavitary structures:
Sensitizer | Positive in both polar and non-polar vehicles

Joint Poster with Sonova at SOT2024:
Unveiling skin sensitization potential: case study on biocompatible material development utilizing the in vitro GARDskin Medical Device assay.

Case study #4A

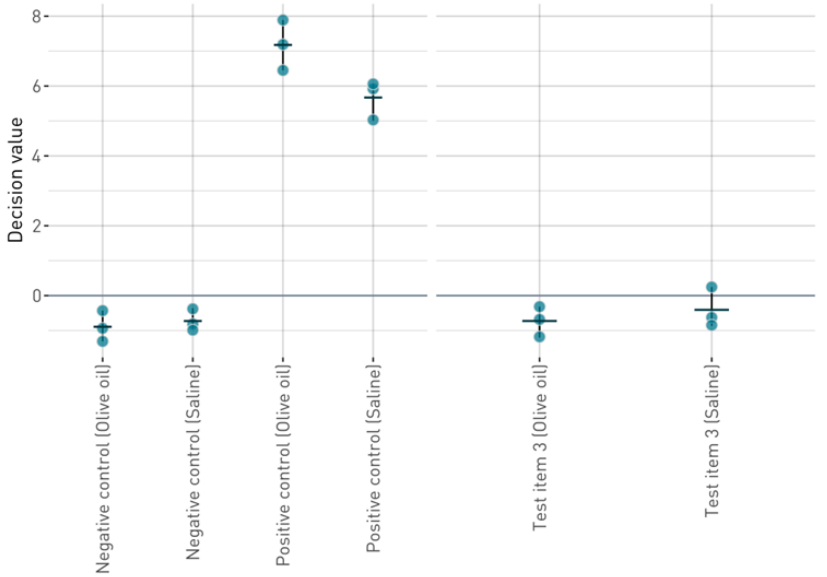
In vitro skin sensitization testing during product development (2/2)

Follow-up testing on an identical device, but without cavities confirmed the hypothesis.

Results follow-up testing

- Negative in both polar and non-polar vehicles.
- Device classified as non-sensitizer.

A modification was made accordingly in manufacturing process of the new lacquer to prevent the presence of lacquer in the cavitary structures of the device.



GARD® results for acrylic-based devices without cavitary structures: Non-sensitizer | Negative in both polar and non-polar vehicles

Case study #4B

In vitro skin sensitization testing during product development (1/2)

Background

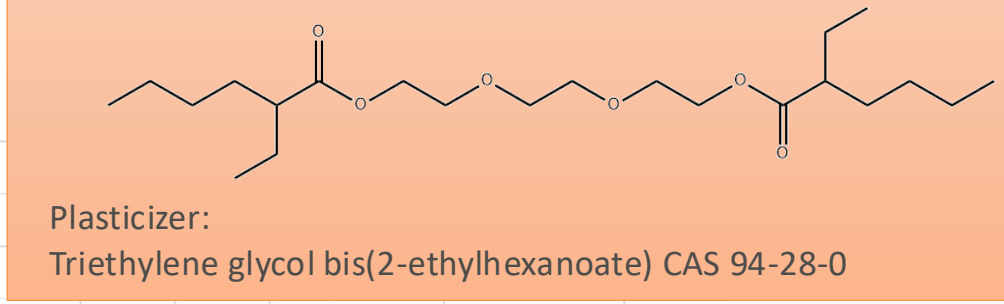
- Cellulose Acetate Propionate (CAP) material for a solid device component.

Methods

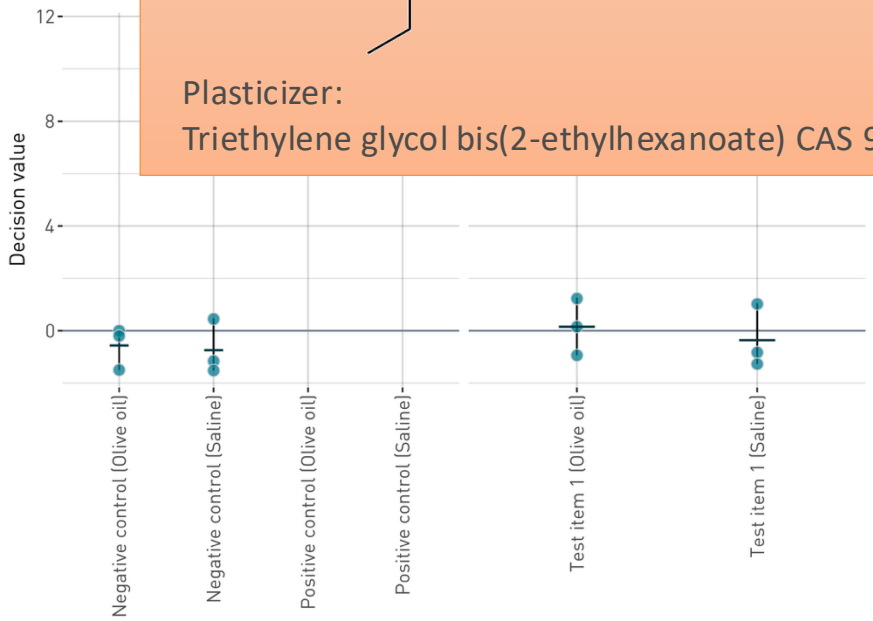
- GARDskin Medical Device
- Material prepared according to ISO 10993-12 in polar and non-polar extraction vehicle (72h, 50°C, 3cm^2/ml).

Results

- Positive in non-polar vehicle and negative in polar vehicle - Labelled as a potential skin sensitizer.
- Not expected from the material itself.



Plasticizer:
Triethylene glycol bis(2-ethylhexanoate) CAS 94-28-0



GARD® results for the CAP material: Sensitizer
| Negative in polar vehicle and Positive in non-polar vehicle

Literature research led to suspect of a plasticizer:
Negative LLNA data (EC3= 2.97), just below classification threshold (SI=3) when tested at 100%, indicating a borderline result.

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Case study #4B

In vitro skin sensitization testing during product development (2/2)

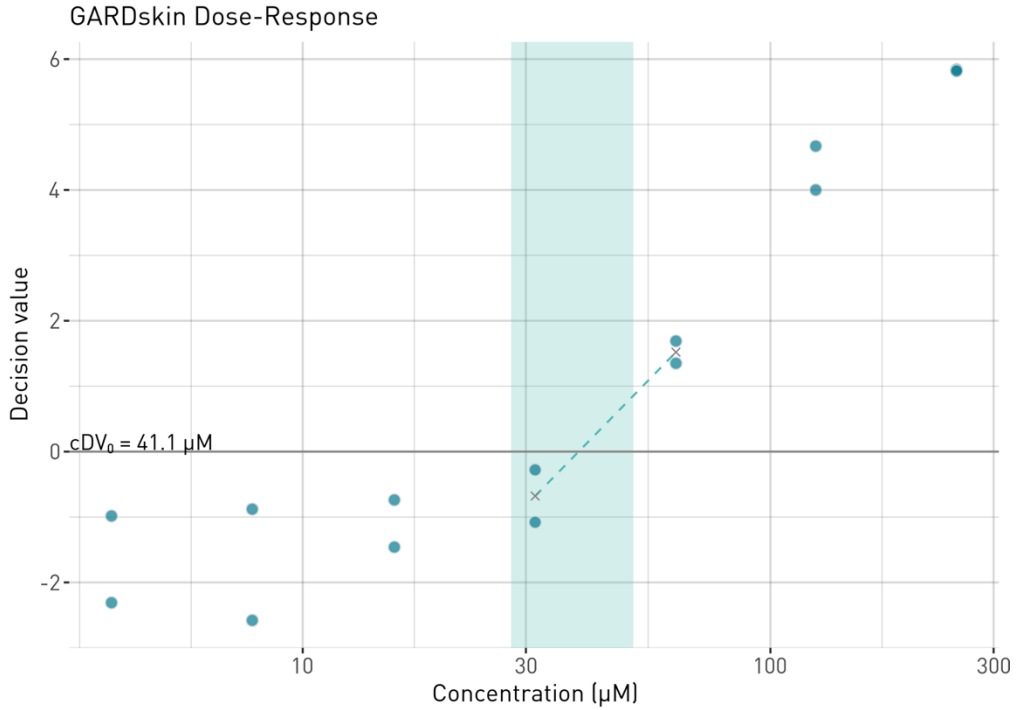
Quantitative potency data from GARD®skin Dose-Response

A follow-up study is performed to confirm this hypothesis, using GARDskin Dose-Response.

Results follow-up study

- The plasticizer is classified as a weak sensitizer.

Quantitative potency data provided by GARDskin Dose-Response confirmed the hypotheses. As a result, a different material was selected.



Results from the GARD®skin Dose-Response assay confirmed the plasticizer as a Weak Sensitizer.

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In vitro skin sensitization testing of medical device and materials with GARD®

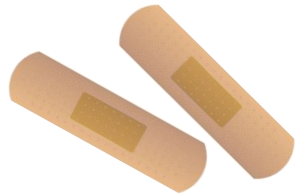
Demonstrated applicability to a wide range of solid materials and medical device extracts, including:

- Polymers, acylates, acrylate monomers
- Coatings, pigments, plasticizers, other additives
- Metals
- Wound dressings
- Disposable hygiene products
- Textiles

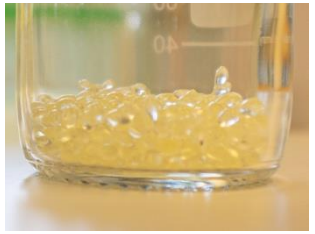

Image source: Sonova















Summary & conclusions

In vitro testing of medical devices according to ISO 10993

Can the "Big Three" be addressed using a non-animal-based testing approach?
Yes, scientifically validated, reproducible and accurate *in vitro* tests are available to address cytotoxicity, skin irritation and skin sensitization. There are few scientific arguments against these methods.

What are the advantages of non-animal-based approaches for biocompatibility testing of medical devices?

- A more ethical approach
- Well-adapted to scaling and shorter turn-around times
- For skin sensitization: *in vitro* methods are much more sensitive resulting in safer products on the market

Is a non-animal-based approach regulatory accepted?
Case study shows the potential to use a non-animal-based approach and to gain approval for CE-marking of products according to MDR.

- **Regulators and industry must be prepared for the transition.** Industry can contribute by submitting existing *in vitro* data and generating dual data only when specifically requested.