Bormed™- expert advice on advanced polyolefins for Medical Technology applications

BOREALIS

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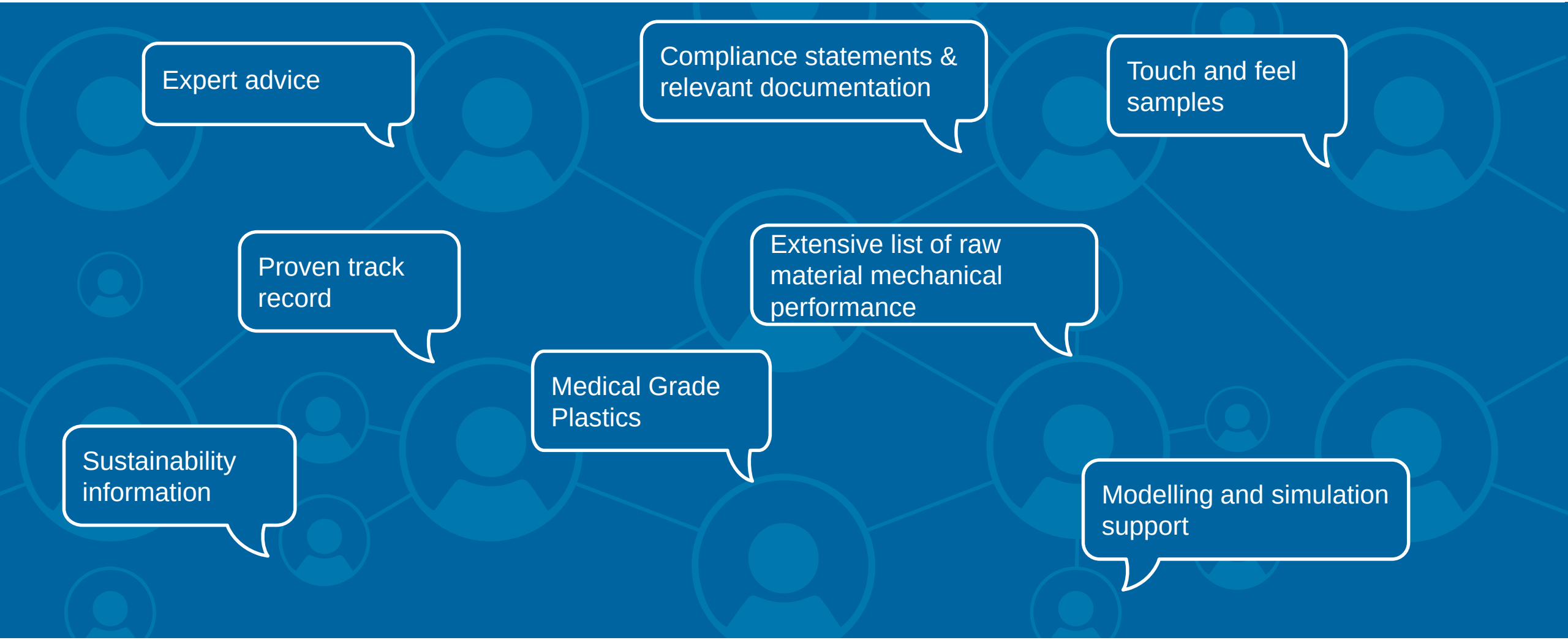
Borouge

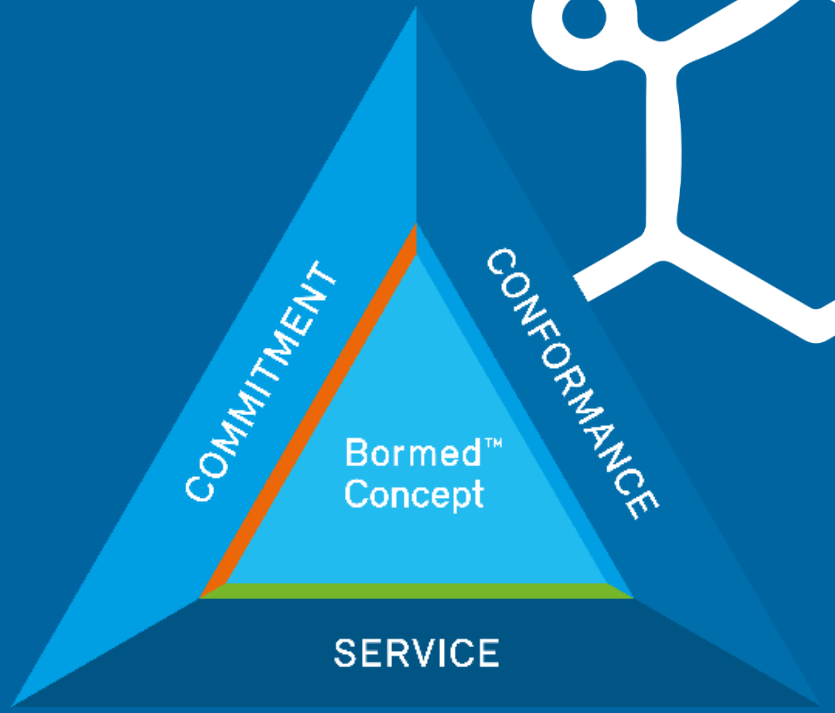
What material and design engineers told us …. a wish list



Bormed™: commitment to the strict industry requirements

COMMITMENT

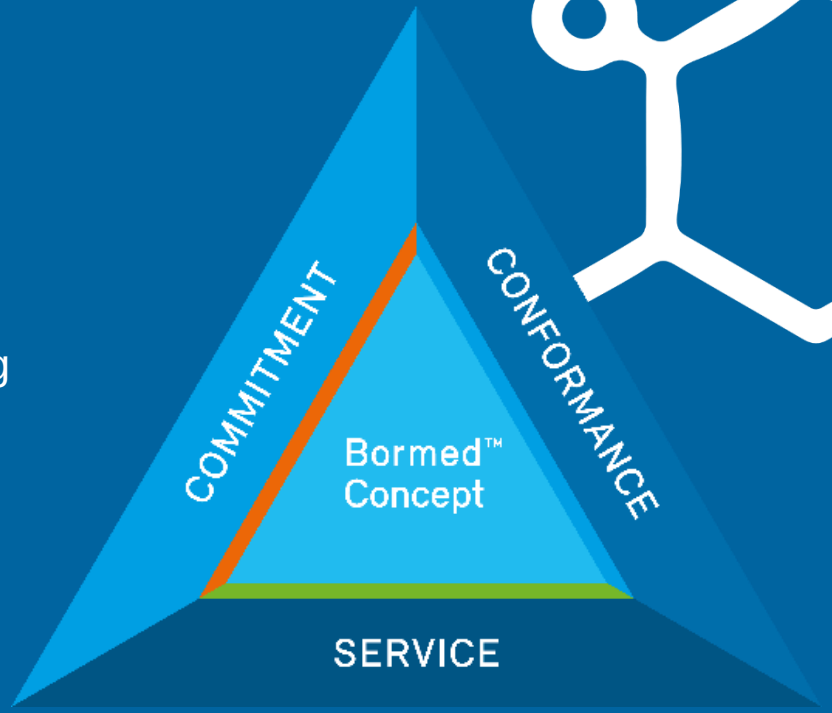
- Dedicated portfolio of branded PE & PP
- Bormed de facto quality agreement - Technical Delivery Specification (TDS)
- Continuity of supply regulated by TDS - Product made available up to 5 years in case of change
- Consistency of the product recipe via rigorous change control procedure
- The Bormed Directive (PO4047): operating instructions for the development, production, storage and delivery to the end customer of Bormed products



Bormed™: conformance to key global standards

CONFORMANCE

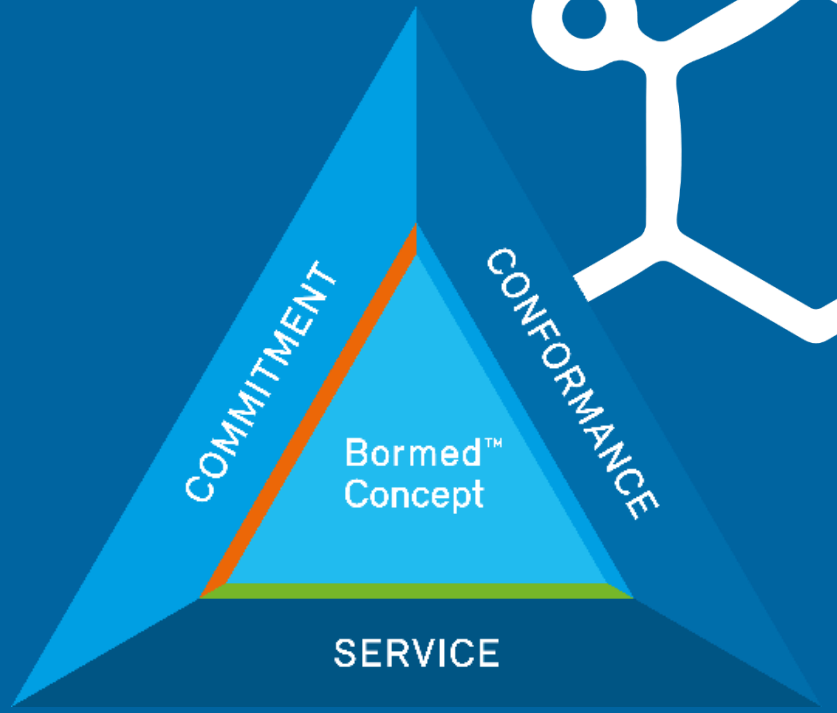
- Pharmacopeia compliance
  - External Ph. Eur., USP (incl. 661.1) and ISO 10993 testing
  - Analysis reports can be shared on request
- DMF listing and issuing LoA
- Following VDI guidelines on medical grade plastics



Bormed™: global support to healthcare service needs

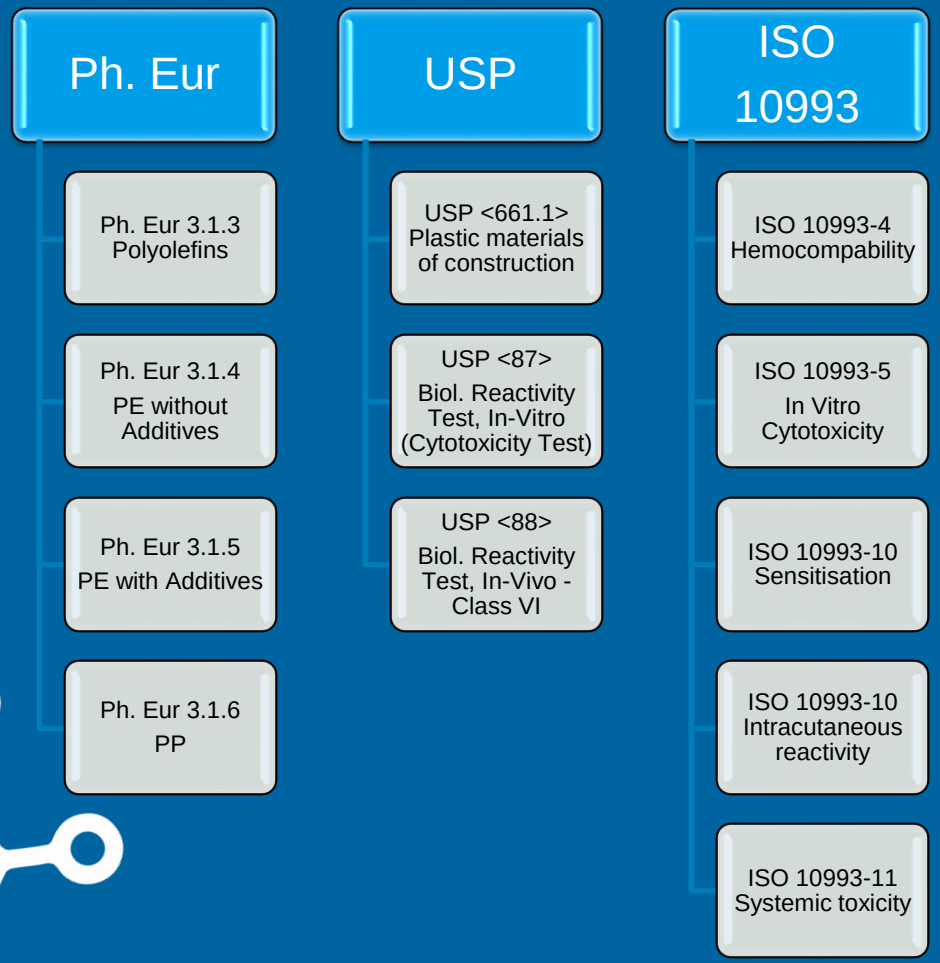
SERVICE

- Extractable profiles that can be shared on request
- Website and MyBorealis portal with comprehensive compliance statements
- Globally available dedicated team of experienced technical and regulatory specialists
- Innovation in products and services relevant for Healthcare industry



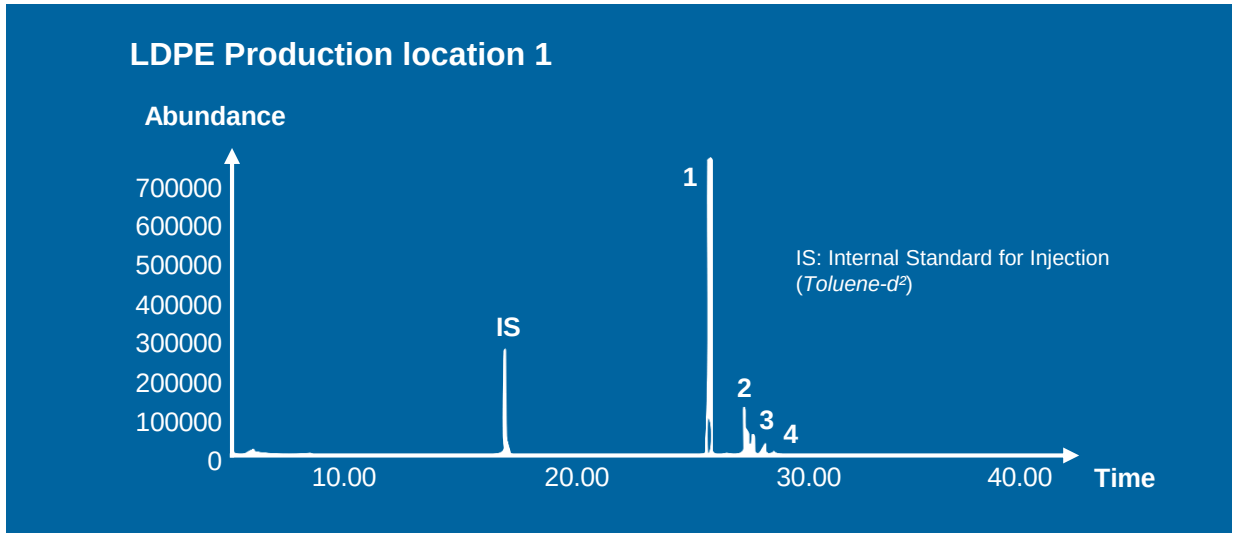
Expert advice

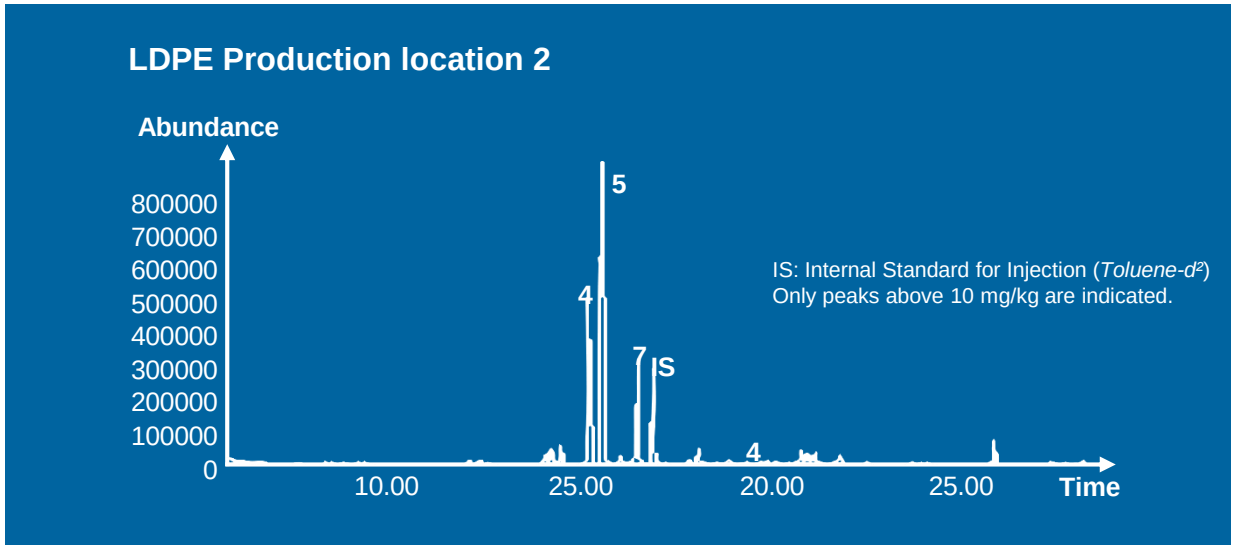
Externally conducted compendial testing available for Bormed



- For your Peace of Mind and even though change management is in place:
  - Yearly external testing of Ph. Eur
  - USP, ISO 10993 external testing every 5 years (as it involves animal testing)
- Analysis reports can be shared on request
- All Bormed grades are US DMF listed: LoA issued upon request

Going the extra mile: our extractable testing





Value for the customer

- Extractive data on resin can support informed decision making and validation at an early stage: time/money saving of customer's testing programme
- Testing programme determined in co-operation with Nelson Labs
- Extraction with 3 solvents: UPW, Ethanol and Hexane
  - Chosen to give the broadest possible dataset whilst still remaining relevant to majority of industry
- Extractable data can be shared under NDA along with composition disclosure (formulation)
- The profile of a few pellets will differ to a moulded and subsequently sterilised container

Bormed™ performance in comparison to other material options

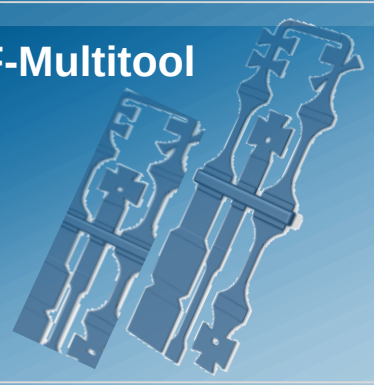
Key Performance Criteria	PP	PC / ABS	ABS	PC	PBT	POM	PA6
Stiffness @ room temp.	1100-1900 MPa	2000-2600 MPa	1300-2700 MPa	2100-2400 MPa	2000-2300 MPa	1600-3200MPa	1000-1400MPa
Yield Strength @ room temp.	25-40MPa	40-60MPa	45-65MPa	55-65MPa	50-60MPa	60-75MPa	45-80MPa
Toughness	Good	Good	Fair	Good	Fair	Fair	Very Good
Transparency	Good	Poor	Poor	Very Good	Poor	Poor	Poor
EtO Sterilisation	Good	Good	Good	Good	Good	Good	Good
Steam Sterilisation @ 121C	Good	Poor	Poor	Fair	Fair	Good	Fair
Radiation Sterilisation	Fair	Good	Good	Good	Good	Poor	Fair
Chemical Resistance	Very Good	Fair	Good	Poor	Fair	Fair	Fair
Processability	Good	Fair	Good	Fair	Fair	Fair	Good
Density	0,90-0,91 gr/cm3	1,08-1,17 gr/cm3	1,03-1,07 gr/cm3	1,20-1,24 gr/cm3	1,30-1,32 gr/cm3	1,41-1,43 grcm3	1,12-1,15 gr/cm3

- Materials with high modulus up to 1900 Mpa
- Grades with excellent balance between high toughness & high flow at low temperature
- Sterilisation compatible grades for EtO, steam at 121ºC and gamma radiation
- Very good chemical resistance

Advanced modelling and simulation support

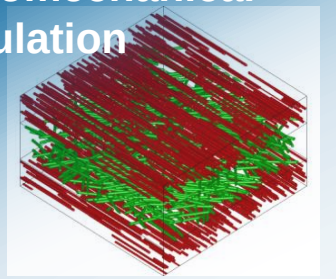
Borealis world of computational material science

GF-Multitool

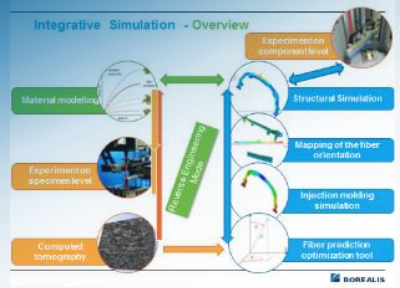


Microstructure

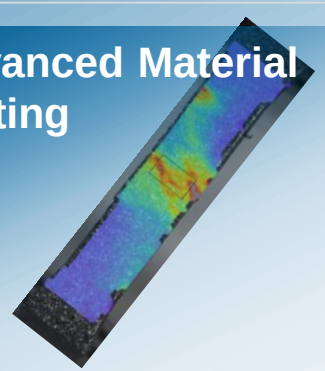
Micromechanical Simulation



Integrative Simulation



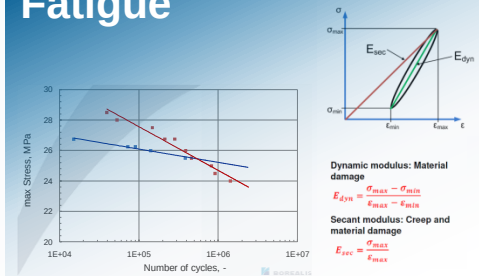
Advanced Material Testing



Damage & Failure

Creep

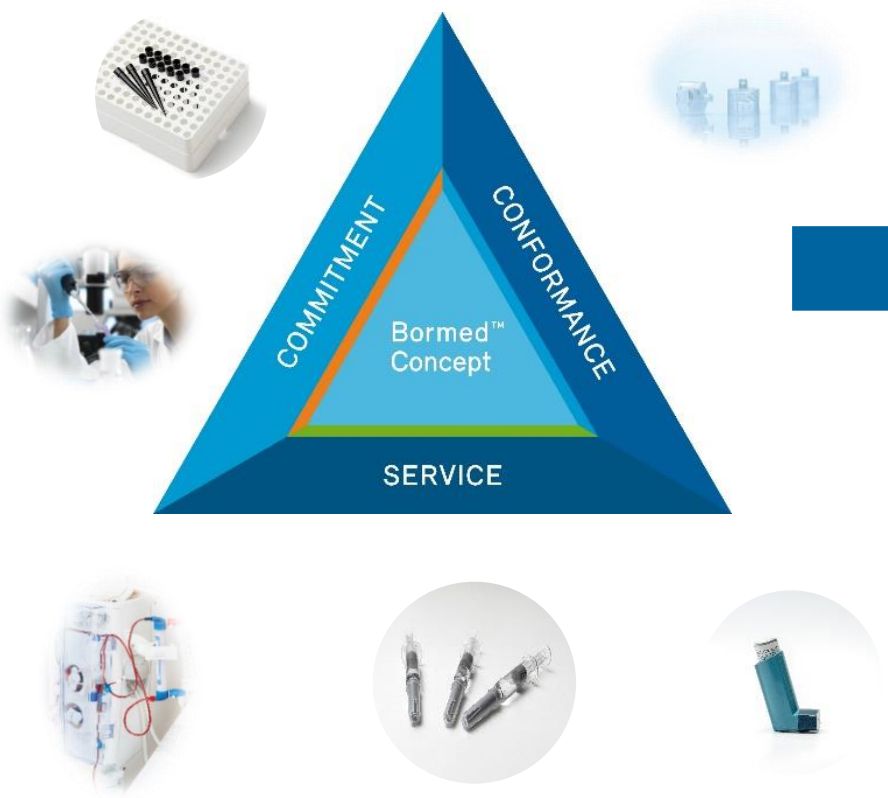
Fatigue



Raw material know-how & benefits

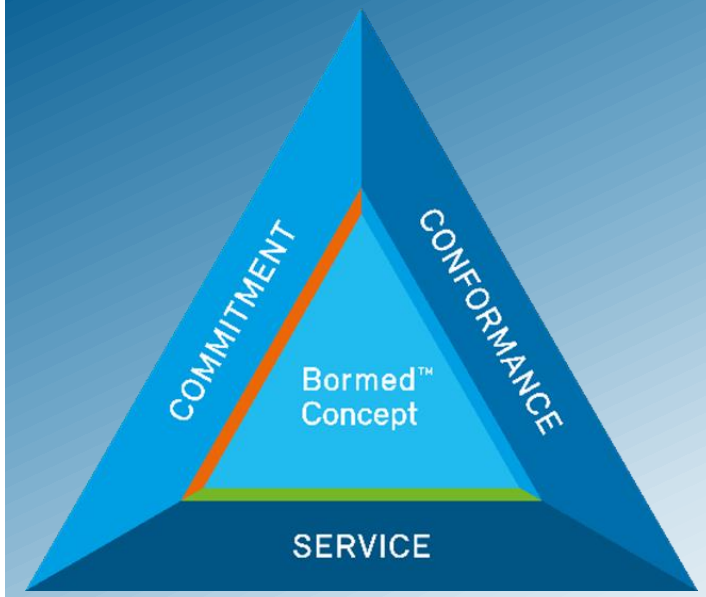
Material needs for medical and diagnostic devices

Determining the key material performance criteria is essential for successful material selection



MATERIAL REQUIREMENTS	
PHYSICAL	**Physical performance elements for robust design** − Stiffness for thin walled sections − High impact strength retention at low temperatures − Transparency − High MFI for multi-cavity tools
REGULATORY	**Compliance to regulatory directives** − Compliance to directives and new EU MDR/IVDR − Regulatory back up support
STERILISATION	**Compatibility with sterilisation method** − EtO − Radiation − Steam /Autoclave
ADDITIVES	**Functional additives for tailor made solution** − Anti-static − Nucleation − Slip agent − Radiation

Broad Bormed™ portfolio for medical and diagnostic devices



- Grades with high modulus up to 1900 Mpa for thin wall and insert sections of medical devices where high stiffness is key for robust design
- Materials with up to 75 g/10 min MFI values for easy flow of material within high cavity tools of diagnostic applications
- Excellent balance between high toughness & high flow at low temperature
- Sterilisation compatible grades for EtO, steam at 121ºC and gamma radiation
- Special additive packages including slip, antistatic, etc.
- High transparency grades for medical devices
- Excellent compounding compatible grades for diagnostics applications

Material needs for medical equipment

Aesthetics follows function

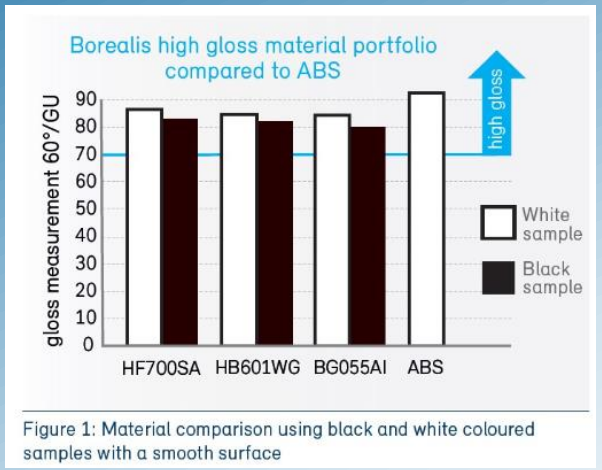


Figure 1: Material comparison using black and white coloured samples with a smooth surface

Borealis materials enable:

- Innovation by increasing design freedom
- Optimising processes
- Enhancing end-use performance
- Pleasant, high gloss aesthetics

Chemical resistance

Key Performance Criteria	PP	ABS	PC
Stiffness @ room temp.	1100-1900 MPa	1300-2700 MPa	2100-2400 MPa
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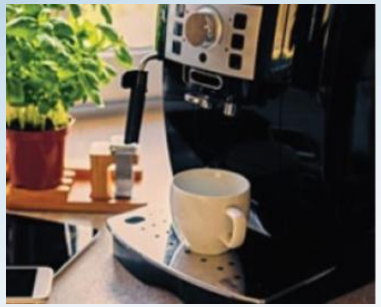
Processability	Good	Good	Fair
Density	0,90-0,91gr/cm3	1,03-1,07gr/cm3	1,20-1,24gr/cm3

- PE and PP are recognised for their excellent resistance to harsh chemical environments
- Attention to part design and mould filling/cooling is also important to minimise moulded-in stresses which can accelerate failure

Examples of Borealis appliance portfolio for medical equipment

HB601WG
– Perfect for visible parts due to excellent surface properties
– Excellent detergent resistance
– Long term thermal stability

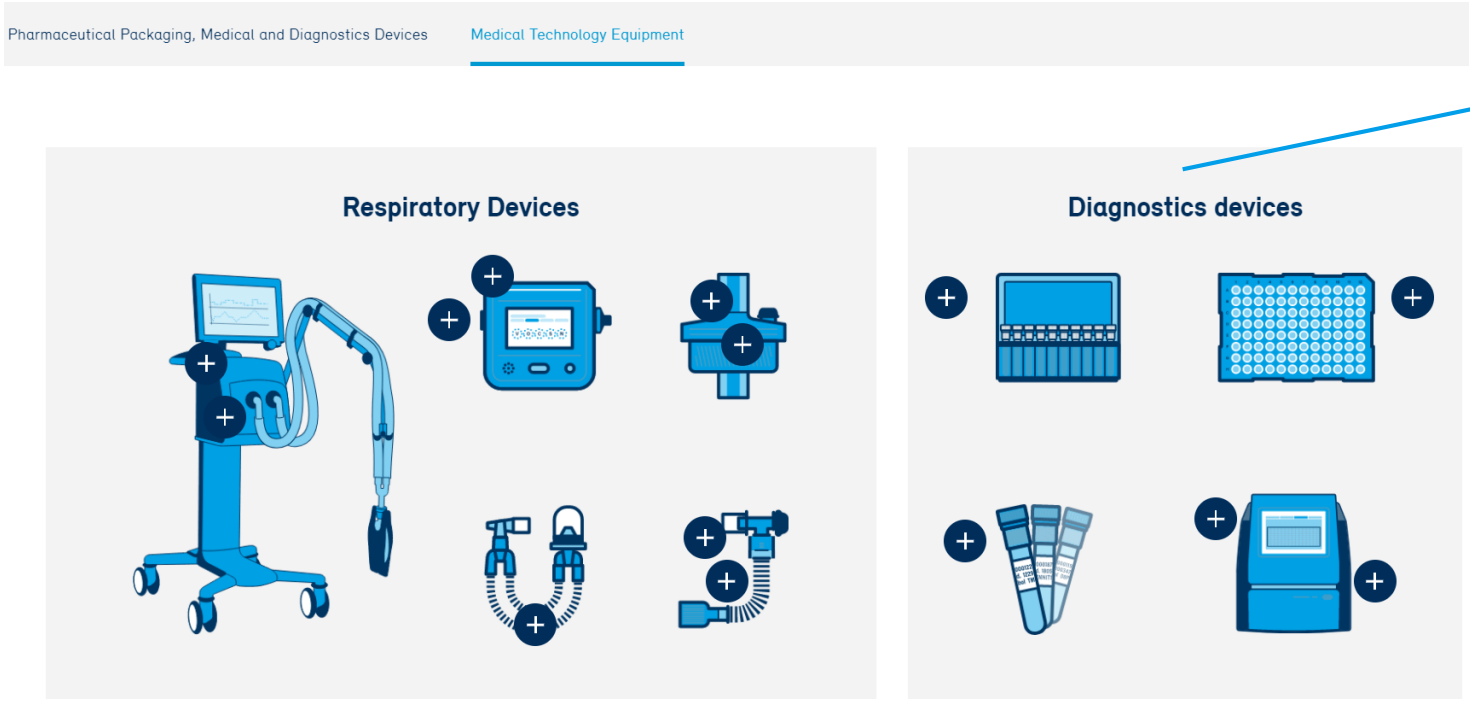


HF700SA
– Good flowability
– High heat stabilised
– Antistatic performance
– Ideal for visible parts where high gloss is essential

BG055AI
– Excellent balance between impact strength and stiffness
– Good flowability
– Ideal for appliances needing high aesthetical requirements like high gloss and scratch resistance

Discover more at our website

https://www.borealisgroup.com/polyolefins/healthcare/medical-technology-equipment



Bormed InCompounds

By partnering with trusted and recognised healthcare compounders, we extend the Bormed reach to compound solutions. In doing so we ensure that every end-customer can get the **requested tailor-made solution based on Bormed**

Partner selection criteria

- To have a healthcare product brand
- Dedicated organisation, e.g. demonstrated through a healthcare marketing manager/business development manager
- ISO13485-2016
- Open for customer audits
- Internal change control procedure available
- Dedicated HC team consisting of application and regulatory experts
- Document management capabilities to meet compliance needs

Our current partners

WITTENBURG GROUP

MOCOM

AVIENT™
PolyOne + Clariant Masterbatch » Better Together

MELITEK

Value chain cooperation key to validation of new solutions

Multifunctional face masks produced by Arburg using Bormed™ BJ868MO

“The great cooperation and quick and easy communication with Borealis as well as the excellent features of BJ868MO have contributed significantly to the success of the project.”

Dr. Thomas WALTHER, Head of Application Engineering, ARBURG

Bormed BJ868MO produces superior quality pipette tips with Plastisud Mold and Sumitomo Demag IM Machine

“Our customers demand perfect straightness as well as superior part quality – and this material delivers! In production, we benefited from a wider process window that enabled us to improve cycle times, and we could reduce injection pressure as well. All in all, this grade is the ideal material for seamless production

Virginie BRYSBAER, Project Manager, PLASTISUD

Sustainability enablers

Circular Economy: introducing the Bornewables and in the near future chemically recycled POs

Solutions for Healthcare

Recyclates	BORCYCLE™			The Bornewables™
	Borcycle™ M	Borcycle™ S	Borcycle™ C	
	 			
Mechanical Recycling	**Advanced Mechanical Recycling**	**Solvent based Recycling**	**Chemical Recycling**	**Renewable-based POs**
Granulates that deliver primarily dark colours with challenges in odour and impurities; not food approved	Recyclates and compounds that overcome challenges of state of the art recyclates: light colours; reduced odour impurities; not food approved	Purity levels close to virgin: transparent; improved processability; further odour improvements; not food approved	– Virgin equivalent – Food approved grade – Offered with the Bormed service package for medical grade plastics	– Virgin equivalent – Food approved grade – Offered with the Bormed service package for medical grade plastics
Not a viable option for most Healthcare applications as not a virgin equivalent and not food approved grades			**First generation demonstration**	**Commercially Available**

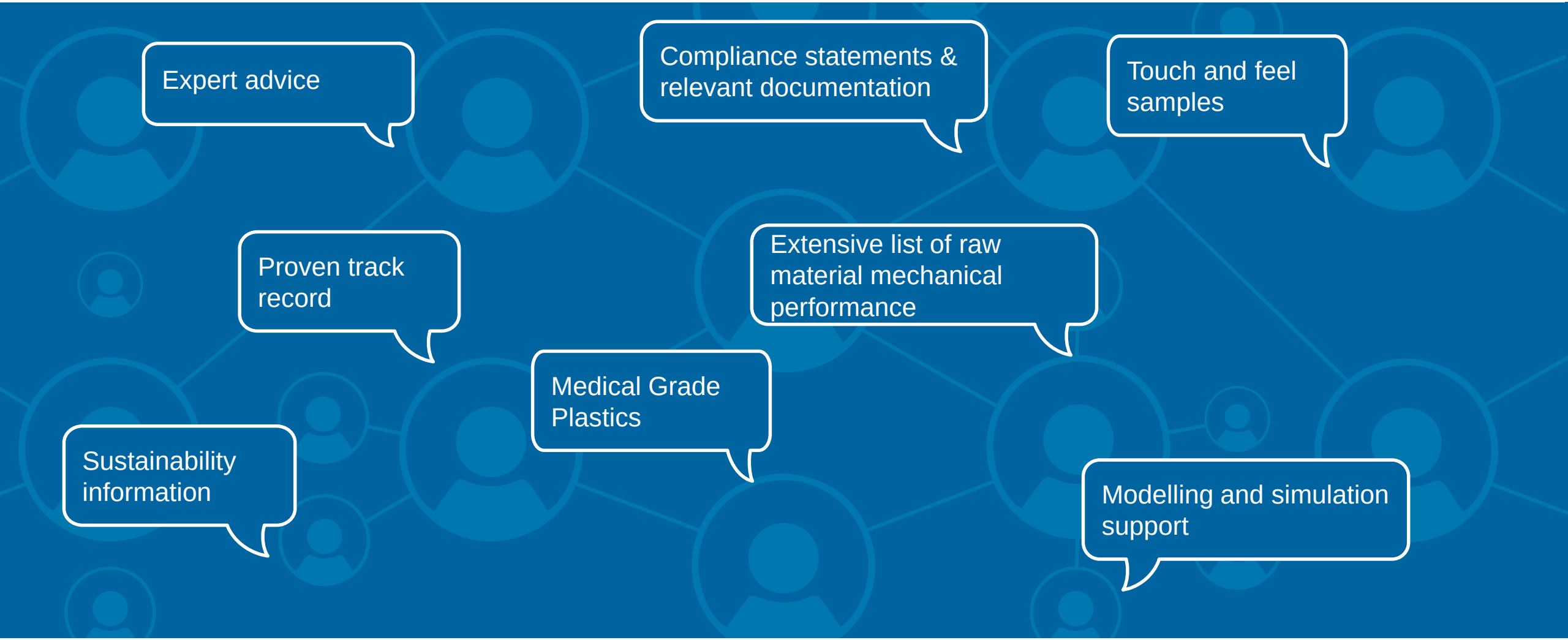
The Bornewables™: Borealis' new line of circular polyolefins produced with renewable feedstock

- First step towards **decoupling from fossil feedstocks**
- Renewable feedstock based on waste and residue streams with proven **lower environmental impact**
- ISCC Plus certification provides traceability throughout the supply chain using the mass balance approach
- The Bornewables are **drop-in solutions**: same technical properties, compliance statements, product safety and recyclability
- With The Bornewables™ portfolio, we deliver on our EverMinds™ promise to spur the **transformation from a linear to a circular economy**.

Borealis commits to lead the transformation to a truly circular economy, because…

Summary

What material and design engineers told us …. a wish list



Thank you